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**NOTICE OF APPEAL FROM THE EXAMINER
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

APPELLANT: Bergersen

ATTY. DOCKET NO.: BER-P-03-054

SERIAL NO.: 10/665,441

GROUP ART UNIT: 3732

DATE FILED: Sept. 18, 2003

EXAMINER: Lewis

INVENTION: "DENTAL APPLIANCES HAVING ATTACHABLE UPPER AND LOWER HALVES
AND SYSTEMS AND METHODS FOR TREATING MALOCCLUSIONS"

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S APPEAL BRIEF TRANSMITTAL LETTER

SIR/MADAM:

Appellant submits herewith Appellant's Appeal Brief in support of the Notice of Appeal filed February 1, 2008 and in response to the Notification of Non-Compliant Appeal Brief dated June 25, 2008. Appellant submits that no fee is required for submission of this Appeal Brief. However, the Commissioner is hereby authorized to charge any fees which may be required, or to credit any overpayment to Deposit Acct. No. 50-0595. A duplicate copy of this sheet is enclosed for this purpose.

Respectfully submitted,

(Reg. No. 35,018)

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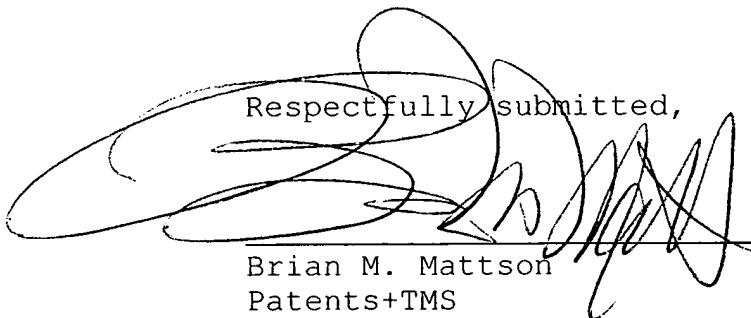
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Attorney for Appellant



CERTIFICATE OF MAILING

I hereby certify that this **APPEAL BRIEF** with **CLAIMS APPENDIX, EVIDENCE APPENDIX, RELATED PROCEEDINGS APPENDIX AND SUPPLEMENTAL APPENDIX CONTAINING EXHIBITS A, B, C and D** are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Mail Stop Appeal Brief Patents, Commissioner for Patents, Alexandria, VA 22313 on July 24, 2008.



Brian M. Mattson (Reg. No. 35,018)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANT: Bergersen

ATTY. DOCKET NO.: BER-P-03-054

SERIAL NO.: 10/665,441

GROUP ART UNIT: 3732

DATE FILED: Sept. 18, 2003

EXAMINER: Lewis

INVENTION: "A SYSTEM OF DENTAL APPLIANCES HAVING VARIOUS SIZES AND TYPES AND A METHOD FOR TREATING MALOCCLUSIONS OF PATIENTS OF VARIOUS AGES WITHOUT ADJUSTMENTS OR APPOINTMENTS"

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

SIR/MADAM:

This Appeal Brief is submitted in support of the Notice of Appeal filed on February 1, 2008 and in response to the Notification of Non-Compliant Appeal Brief dated June 25, 2008. The Appeal is taken from the Final Rejection dated December 28, 2007.

I. REAL PARTY IN INTEREST

Ortho-Tain, Inc. is the real party in interest in this Appeal.

II. RELATED APPEALS AND INTERFERENCES

U.S. Patent Application Serial Number 10/447,099 filed on May 28, 2003, U.S. Patent Application Serial Number 10/449,292 filed on May 30, 2003 and U.S. Patent Application Serial No. 10/449,312 filed on May 30, 2003 are currently on appeal and may directly affect, may be directly affected by, or may have a bearing on the

Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-87 are pending in this patent application. Claims 21-34 were withdrawn from consideration. Claims 1-20 and 35-87 were finally rejected by the Examiner in a Final Rejection dated December 28, 2007 and are hereby on appeal. A copy of the claims which are subject to this appeal are appended hereto as the Claims Appendix. The Final Rejection is appended hereto as Exhibit A of the Supplemental Appendix.

IV. STATUS OF AMENDMENTS

All amendments have been entered in this patent application. No amendments to the claims were made after the Final Rejection.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention provides a system of dental appliances having various sizes and types which may be used to treat a child, an adolescent and/or an adult patient to obtain a satisfactory orthodontic result without adjustments or appointments.

Independent Claim 1 defines a dental appliance adapted to be worn in a mouth of a user having one or more types of teeth. Claim 1 requires a generally U-shaped base having a flat occlusal surface (page 3, lines 29-32) wherein the flat occlusal surface is shaped to contact the teeth wherein the base is preformed (page 21, lines 21-26) and has a length defined between a first end and a second end; a first wall extending from the flat surface wherein the first

wall defines an interior surface (page 3, line 32 to page 4, line 1); a second wall extending from the flat surface wherein the second wall defines an exterior surface (page 4, lines 1-3); a wire (190, FIG. 32; page 29, lines 2-7; 320, FIGS. 29, 30A and 30B; page 33, line 26 to page 34, line 16) embedded within the base wherein one of the teeth has a first side and a second side wherein the second side is positioned opposite to the first side wherein the wire extends vertically from the base adjacent to the first side of the tooth and does not extend from the base adjacent to the second side of the tooth (FIG. 32; page 34, lines 11-14); and a slot (page 21, lines 21-26) in the base wherein the slot is defined between the first wall and the second wall wherein the slot extends along the length of the base from the first end of the base to the second end of the base wherein the slot defines a width of the flat occlusal surface wherein the width of the slot increases from a first portion of the slot to a second portion of the slot (FIG. 2; page 23, lines 5-19) wherein the first portion of the slot is shaped to contact a front of the mouth wherein the second portion of the slot is shaped to extend rearward in the mouth and further wherein the second portion of the slot is sized to receive canine type of teeth of the user wherein the second portion of the slot is shaped to move the canine type of teeth when the base is worn by the user wherein the second portion of the slot is shaped to correct the malocclusion of the canine type teeth (page 4, lines 1-

12).

Independent Claim 8 defines a method for correcting a dentition in a mouth of a user having one or more types of teeth wherein one of the types of teeth is canine teeth. Claim 8 requires providing a generally U-shaped base having a first socket (page 21, lines 21-32) that receives the canine teeth; contacting the canine teeth with the generally U-shaped base wherein the generally U-shaped base contacts the canine teeth on an outer side of the canine teeth and on an inner side of the canine teeth wherein the inner side of the canine teeth is opposite in position to the outer side wherein the socket has an occlusal surface (page 3, lines 29-32); forming wedges (152, 154, FIG. 14; page 26, line 28 to page 27, line 3) within the first socket wherein each of the wedges extend outward with respect to the occlusal surface of the first socket to form an apex shaped to extend toward a canine tooth that is one of the canine teeth and to contact the canine tooth wherein the wedges contact an interproximal area of the canine tooth wherein the interproximal area is located between the canine tooth and a second tooth and further wherein the wedge does not contact any area of the canine tooth other than the interproximal area (152, 154, FIG. 14; page 26, line 28 to page 27, line 3); and moving the canine tooth with the wedge when the base is worn by the user.

Independent Claim 14 defines a method for correcting a

dentition in a mouth of a user having teeth. Claim 14 requires a generally U-shaped base; sockets (page 21, lines 21-32) within the base wherein at least one of the sockets is preformed (page 21, lines 21-26) wherein at least one of the sockets has peripheral walls defining an interior wherein the interior is shaped to receive a first tooth wherein the peripheral walls separate a first tooth from a second tooth wherein the sockets are shaped to treat a malocclusion; and applying pressure to one side of the first tooth with a wire (190, FIG. 32; page 29, lines 2-7; 320, FIGS. 29, 30A and 30B; page 33, line 26 to page 34, line 16) embedded within the base wherein the wire extends vertically from the base and contacts the first tooth only on the one side of the first tooth (FIG. 32; page 34, lines 11-14).

Independent Claim 35 defines a dental appliance adapted to be worn in a mouth of a user having teeth. Claim 35 requires a generally U-shaped base having an occlusal surface (page 3, lines 29-32) wherein the occlusal surface contacts the teeth when the dental appliance is worn by the user; a first wall extending from the occlusal surface wherein the first wall defines an interior surface (page 3, line 32 to page 4, line 1); a second wall extending from the occlusal surface wherein the second wall defines an exterior surface (page 4, lines 1-3) and wherein the first wall and the second wall define a width of the occlusal surface; a liquid within the generally U-shaped base wherein the liquid is

released from the generally U-shaped base (page 29, lines 7-14); and a wire (190, FIG. 32; page 29, lines 2-7; 320, FIGS. 29, 30A and 30B; page 33, line 26 to page 34, line 16) embedded within the base wherein the wire extends vertically from a top surface of the second wall toward the teeth when the base is worn by the user wherein the wire is shaped to contact a labial side of a first tooth (FIG. 32; page 34, lines 11-14) wherein the first tooth is an incisor type tooth.

Independent Claim 44 defines a dental appliance adapted to be worn in a mouth of a user having one or more types of teeth. Claim 44 requires a generally U-shaped base having a flat occlusal surface (page 3, lines 29-32) wherein the occlusal surface is shaped to contact the teeth; at least one socket (page 21, lines 21-32) within the occlusal surface wherein each socket has a first wall (page 3, line 32 to page 4, line 1) and a second wall (page 4, lines 1-3) wherein the second wall separates a first tooth from a second tooth wherein the socket is sized based on anatomical standards for teeth wherein at least one socket is shaped to receive canine type teeth regardless of anatomical variations of the canine type teeth of the user (page 25, lines 26-33); and a wire (190, FIG. 32; page 29, lines 2-7; 320, FIGS. 29, 30A and 30B; page 33, line 26 to page 34, line 16) embedded within the base wherein the wire is shaped to contact only a labial side of one of the teeth (FIG. 32; page 34, lines 11-14).

Independent Claim 52 defines a method for diagnosing an orthodontic condition of a patient. Claim 52 requires providing an analysis means for the patient to analyze a position of one or more teeth within a mouth of the patient wherein a width of the mouth is measured by the analysis means (FIGS. 31A and 31B; page 31, line 17 to page 35, line 24); displaying a tooth arrangement to which the patient compares the position of the one or more teeth (FIGS. 31A and 31B; page 31, line 17 to page 35, line 24); and distributing a dental appliance to the patient after the patient compares the position of the one or more teeth wherein a size of the dental appliance corresponds to the width of the mouth wherein the dental appliance is constructed from a first material and a second material wherein the first material is softer than the second material wherein a first portion of the dental appliance is constructed from the first material and contacts a first set of teeth and a second portion of the dental appliance is constructed from a second material and contacts a second set of teeth wherein the first set of teeth and the second set of teeth are different sets of teeth wherein the dental appliance has a front end and further wherein the first portion is located in a first position relative to the front end and the second portion is located in a second position relative to the front end and the first position and the second position are different positions (page 35, lines 11-25).

Independent Claim 58 defines a dental appliance adapted to be worn in a mouth of a user having teeth wherein a first tooth is a canine tooth. Claim 58 requires a generally U-shaped base having an occlusal surface (page 3, lines 29-32) which is shaped to contact the teeth when the base is worn by the user wherein the occlusal surface has a first area wherein the first area is sized to receive the canine tooth wherein the first area is shaped to receive the canine teeth regardless of anatomical variations of canine type teeth of the user wherein the generally U-shaped base has an exterior surface; an incisal edge (82, 84, FIG. 8; page 24, lines 32-33; 74, 76, FIG. 7; page 25, lines 9-19) within the first area of the occlusal surface wherein the incisal edge inclines outward with respect to the occlusal surface and wherein the incisal edge is sized to contact the canine tooth and further wherein the incisal edge is shaped to move the canine tooth wherein the incisal edge is shaped to prevent a malocclusion of the teeth of the user wherein a first portion of the device is constructed from a first material and contacts a first set of teeth and a second portion of the device is constructed from a second material that is softer than the first material and contacts a second set of teeth wherein the second portion of the device has the incisal edge wherein the first set of teeth and the second set of teeth are different sets of teeth (page 35, lines 11-25); and a wire (190, FIG. 32; page 29, lines 2-7; 320, FIGS. 29, 30A and 30B; page 33,

line 26 to page 34, line 16) embedded within the base wherein the wire extends vertically from the exterior surface of the generally U-shaped base toward a tooth when the base is worn by the user wherein the wire is shaped to contact only one side of the tooth (FIG. 32; page 34, lines 11-14).

Independent Claim 63 defines a method for treating a malocclusion in a mouth of a user having one or more types of teeth. Claim 63 requires designing a generally U-shaped base having a flat occlusal surface (page 3, lines 29-32) wherein the flat occlusal surface is shaped to contact the teeth of the user wherein the base has a length defined between a first end and a second end; forming a first wall extending from the flat surface wherein the first wall defines an interior surface (page 3, line 32 to page 4, line 1); forming a second wall extending from the flat surface wherein the second wall defines an exterior surface (page 4, lines 1-3); forming a slot (page 21, lines 21-26) in the base wherein the slot is located between the first wall and the second wall wherein the slot extends along the length of the base from the first end of the base to the second end of the base wherein the slot defines a width of the flat occlusal surface (page 3, lines 29-32) wherein the slot has a first portion, a second portion, a third portion and a fourth portion (page 20, line 6 to page 21, line 1) wherein the second portion is rearward in the mouth of the user with respect to the first portion wherein the third portion is

rearward in the mouth of the user with respect to the second portion wherein the fourth portion is rearward in the mouth with respect to the third portion-wherein the first portion is sized to receive an incisor type of tooth wherein the fourth portion is sized to receive a molar type of tooth of the user and further wherein the second portion and the third portion are shaped to contact teeth located between the incisor type of tooth (page 20, line 6 to page 21, line 1) and the molar type of tooth wherein the slot corrects a malocclusion of the teeth; continuously increasing the width of the slot from the first portion to the fourth portion (FIG. 2; page 23, lines 5-19); and forming wedges (152, 154, FIG. 14; page 26, line 28 to page 27, line 3) within the slot wherein the wedges extend outward with respect to the occlusal surface to form an apex which contacts the teeth.

Independent Claim 68 defines a method for treating a malocclusion in a mouth of a user having one or more types of teeth. Claim 68 requires designing a generally U-shaped base having a flat occlusal surface (page 3, lines 29-32) wherein the flat occlusal surface is shaped to contact the teeth and further wherein the base is preformed (page 21, lines 21-26); forming a first pre-formed socket and a second pre-formed socket (page 21, lines 21-32) within the flat occlusal surface wherein the first socket is sized to receive a canine type tooth wherein the second socket is shaped to receive at least one of the teeth which is not

the canine type of teeth of the user; separating the canine type tooth from teeth which are not the canine type of teeth wherein the first socket separates the canine type tooth from teeth which are not the canine type of teeth wherein the first socket moves the canine type tooth with respect to the teeth when the base is worn by the user; and contacting the canine type tooth with a wire (190, FIG. 32; page 29, lines 2-7; 320, FIGS. 29, 30A and 30B; page 33, line 26 to page 34, line 16) embedded in the base wherein the wire extends from the base and contacts the canine type tooth only on one side of the canine type tooth (FIG. 32; page 34, lines 11-14).

Independent Claim 74 defines a method for correcting a malocclusion in a mouth of a user having teeth. Claim 74 requires providing a generally U-shaped base; forming sockets (page 21, lines 21-32) within the base wherein one of the sockets receives at least one of the teeth of the user wherein at least one of the sockets is sized to receive a canine type tooth (FIG. 13; page 26, lines 26-28) and separates the canine type tooth from the teeth of the user which are not canine type teeth; shaping the socket to move the canine type tooth from a first position to a second position wherein the second position is closer to a front of the mouth of the user than the first position when the base is worn by the user; attaching a liner (160, 162, FIG. 16; page 27, lines 8-15) in one of the sockets wherein the liner has a thickness defined between a top surface and a bottom surface wherein the bottom

surface of the liner attaches to at least one of the sockets wherein the top surface of the liner contacts the teeth when the base is worn by the user wherein the liner is shaped to contact the teeth and wherein the liner prevents movement of the base away from the teeth when the base is worn in the mouth of the user; forming wedges (152, 154, FIG. 14; page 26, line 28 to page 27, line 3) on the base; and contacting an interproximal area of one of the teeth with the wedges wherein the interproximal area is located between adjacent teeth and further wherein the wedge does not contact any area of the tooth other than the interproximal area wherein the wedge moves the tooth (152, 154, FIG. 14; page 26, line 28 to page 27, line 3).

Independent Claim 79 defines a dental appliance adapted to be worn in a mouth of a user having one or more types of teeth. Claim 79 requires a generally U-shaped base having a flat occlusal surface (page 3, lines 29-32) wherein the flat occlusal surface contacts the teeth when the base is worn by the user; a socket (page 21, lines 21-32) within the flat occlusal surface wherein the socket is shaped to receive one or more of the teeth of the user; a first portion of the device having the socket wherein the first portion of the device is constructed from a first material; a second portion of the device constructed from a second material wherein the second portion of the device is different than the first portion of the device and the second material is harder than

the first material (page 35, lines 11-25); a rib (200, 202, FIG. 20; page 29, lines 16-23) on the flat occlusal surface wherein the rib is shaped to contact one or more of the teeth wherein the rib is positioned to contact an interproximal area of at least one tooth of the user when the base is worn by the user wherein the interproximal area is located between a first tooth and a second tooth and further wherein the rib guides one or more teeth of the user toward a position correcting a malocclusion of the teeth of the user when the base is worn by the user; and a wire (190, FIG. 32; page 29, lines 2-7; 320, FIGS. 29, 30A and 30B; page 33, line 26 to page 34, line 16) embedded in the base wherein the wire extends from the socket and further wherein the wire extends from only one side of the socket (FIG. 32; page 34, lines 11-14).

Independent Claim 85 defines a dental appliance adapted to be worn in a mouth of a user having one or more types of teeth. Claim 85 requires a generally U-shaped base having a flat occlusal surface (page 3, lines 29-32) wherein the flat occlusal surface is shaped to contact the teeth of the user wherein the base is preformed (page 21, lines 21-26) and designed from a digital model by a computer wherein the base is sized to correspond to the digital model wherein the digital model corresponds to the teeth of the user; sockets (page 21, lines 21-32) within the flat occlusal surface wherein the sockets have outer surfaces wherein one of the sockets is sized to receive one or more teeth of the user wherein

at least one of the sockets separates a first tooth from a second tooth wherein at least one of the sockets is sized to receive a canine type tooth and to move the canine type tooth with respect to the teeth when the base is worn by the user (FIG. 13; page 26, lines 26-28); and a wire (190, FIG. 32; page 29, lines 2-7; 320, FIGS. 29, 30A and 30B; page 33, line 26 to page 34, line 16) embedded in the base wherein the wire extends from the outer surface of one of the sockets wherein the wire contacts the first tooth and further wherein the wire extends from only one side of the socket (FIG. 32; page 34, lines 11-14).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 1-20 and 35-87 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1-110 of co-pending U.S. Patent Application Serial No. 10/447,099; Claims 1-114 of co-pending U.S. Patent Application Serial No. 10/449,292; Claims 1-139 of co-pending U.S. Patent Application Serial No. 10/449,312; Claims 1-82 of co-pending U.S. Patent Application Serial No. 10/760,604; and Claims 1-51 of co-pending U.S. Patent Application Serial No. 11/257,330.

2. Claims 1-6, 8-12, 14, 16, 17, 19, 20, 35-39, 44-51, 58-66 and 68-87 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,645,420 to *Bergersen* (hereinafter "the '420 patent"). See the '420 patent attached as Exhibit B of the Supplemental Appendix.

3. Claims 7, 13, 43, 52-57 and 85-87 were rejected under 35 U.S.C. §103(a) as being unpatentable over the '420 patent.

4. Claims 15, 40 and 67 were rejected under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view U.S. Patent No. 4,591,341 to *Andrews*. See *Andrews* attached as Exhibit C of the Supplemental Appendix.

5. Claims 6, 42 and 66 were rejected under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view U.S. Patent No. 5,328,362 to *Watson et al.* See *Watson et al.* attached as Exhibit D of the Supplemental Appendix.

VII. ARGUMENT

A. THE PROVISIONAL REJECTION OF CLAIMS 1-20 AND 35-87 FOR NON-STATUTORY DOUBLE PATENTING

Claims 1-20 and 35-87 were rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over Claims 1-110 of co-pending U.S. Patent Application Serial No. 10/447,099; Claims 1-114 of co-pending U.S. Patent Application Serial No. 10/449,292; Claims 1-139 of co-pending U.S. Patent Application Serial No. 10/449,312; Claims 1-82 of co-pending U.S. Patent Application Serial No. 10/760,604; and Claims 1-51 of co-pending U.S. Patent Application Serial No. 11/257,330.

Appellant submits that Claims 1-20 and 35-87 distinctly define the present invention in view of the co-pending applications. The Examiner admits the conflicting claims are not identical but contends Applicant merely re-arranges the order of the claimed

elements and uses different wording (Office Action, p. 3). Appellant asserts that the subject matter of the pending claims of U.S. Serial Nos. 10/447,099; 10/449,292; 10/449,312; 10/760,604; and 11/257,330 is distinct from the subject matter of the pending claims of the present application. The co-pending applications each fail to disclose at least one element required by the current claims of this application. Therefore, Appellant asserts that Claims 1-20 and 35-87 should not have been rejected for obviousness-type double patenting rejections in view of co-pending claims of U.S. Serial Nos. 10/447,099; 10/449,292; 10/449,312; 10/760,604; and 11/257,330.

If the Board of Appeals maintains this rejection, Appellant will file a Terminal Disclaimer upon determination that the claims are otherwise allowable.

**B. THE CITED REFERENCES AND REJECTIONS OF CLAIMS 1-6,
8-12, 14, 16, 17, 19, 20, 35-39, 44-51,
58-66 and 68-87 UNDER 35 U.S.C. §102(b)**

Independent Claims 1, 8, 35, 44, 52, 58, 63, 68, 74, 79 and 85 and dependent Claims 2-6, 9-12, 14, 16, 17, 19, 20, 36-39, 45-51, 59-62, 64-66, 69-73, 75-78, 80-84, 86 and 87 stand rejected under 35 U.S.C. §102(b) as being anticipated by the '420 patent.

In the Final Rejection, the Examiner stated:

In regard to the newly added limitation of claim 1 that there is a wire embedded in the base and extending vertically from the base along one side of a tooth, applicant's attention is drawn to Figures 13 and 14 of Bergersen '420 where such a feature is clearly shown. [...] Additionally, in

regard to claims 41 and 42, Bergersen '420 discloses a second portion 60 of the device which is made of a softer material and which contacts a second set of teeth which is different from the first set of teeth which are not contacted by the softer material 60.

(See Final Rejection, Page 4 of Exhibit A of the Supplemental Appendix.)

**C. CLAIMS 1-6, 8-12, 14, 16, 17, 19, 20, 35-39, 44-51,
58-66 and 68-87 ARE NOT ANTICIPATED BY THE
CITED REFERENCE UNDER 35 U.S.C. §102(b)**

With respect to the rejection of Claims 1-6, 8-12, 14, 16, 17, 19, 20, 35-39, 44-51, 58-66 and 68-87 under 35 U.S.C. §102(b) as being anticipated by the '420 patent, Appellant respectfully submits that the claims distinctly define the present invention from the '420 patent for the reasons that follow.

The Examiner identified element 104 in the '420 patent as the claimed embedded wire; however, the element 104 does not meet the limitations of the embedded wire because the element 104 does not extend vertically from the base. In contrast to the claimed invention, the wire of the '420 patent is completely inside the appliance and helps the appliance maintain its shape. (See the '420 patent, FIG. 14 and Col. 10, lines 4-10). The Examiner states that "the inherent resiliency of the embedded wire would serve to help clasp the appliance to the patient's teeth", but the claims require the structural feature of the wire extending vertically from the base.

Further, the '420 patent merely teaches use of the second

material as a liner on the interior of the first material to receive teeth based on their specific individual shapes (the '420 patent, column 7, line 43 through column 8, line 44, and Figs. 6 and 7). The inner surfaces of the appliance are modified by reshaping selected tooth depressions to the outer contour of their respective teeth, to thereby hold those selected teeth in a precise position. The reshaping is accomplished by introducing soft moldable material into the selected depressions. Contrary to Appellant's claimed invention, the '420 patent fails to teach use of the different materials in sections that contact different teeth. The '420 patent merely teaches use of different materials within the same socket, as different layers of the appliance (see the '420 patent, FIGS. 6-9). Contrary to the allegations of the Examiner, the '420 patent fails to teach use of the different materials in sections that contact different teeth (compare FIGS. 6-9 of the '420 patent to FIG. 10 of the application at issue).

Still further, the Office Action does not address the requirement of Claim 1 that the width of the slot increases from a first portion of the slot to a second portion of the slot wherein the first portion of the slot is shaped to contact a front of the mouth wherein the second portion of the slot is shaped to extend rearward in the mouth. The '420 patent discloses troughs with sockets, not a slot that has an increased width rearward in the slot.

Moreover, the Examiner identified element 22 in '420 patent as the claimed wedge; however, element 22 does not meet the limitations of the wedge because element 22 does not extend from the socket or slot to contact only an interproximal area of teeth. As admitted in the Office Action, the alleged wedge is located "all the way around" the tooth, "including its sides". (See Office Action, p. 5).

The '420 patent fails to disclose a wire embedded within the base wherein the wire extends vertically from the base adjacent to the first side of the tooth and does not extend from the base adjacent to the second side of the tooth as required by independent Claim 1.

The '420 patent fails to disclose forming wedges within the first socket wherein each of the wedges extend outward with respect to the occlusal surface of the first socket to form an apex shaped to extend toward a canine tooth that is one of the canine teeth and to contact the canine tooth wherein the wedges contact an interproximal area of the canine tooth wherein the interproximal area is located between the canine tooth and a second tooth and further wherein the wedge does not contact any area of the canine tooth other than the interproximal area; and moving the canine tooth with the wedge when the base is worn by the user as required by independent Claim 8.

The '420 patent fails to disclose applying pressure to one

side of the first tooth with a wire embedded within the base wherein the wire extends vertically from the base and contacts the first tooth only on the one side of the first tooth as required by independent Claim 14.

The '420 patent fails to disclose a wire embedded within the base wherein the wire extends vertically from a top surface of the second wall toward the teeth when the base is worn by the user wherein the wire is shaped to contact a labial side of a first tooth wherein the first tooth is an incisor type tooth as required by independent Claim 35.

The '420 patent fails to disclose a wire embedded within the base wherein the wire is shaped to contact only a labial side of one of the teeth as required by independent Claim 44.

The '420 patent fails to disclose that a first portion of the device is constructed from a first material and contacts a first set of teeth and a second portion of the device is constructed from a second material that is softer than the first material and contacts a second set of teeth wherein the first set of teeth and the second set of teeth are different sets of teeth; and a wire embedded within the base wherein the wire extends vertically from the exterior surface of the generally U-shaped base toward a tooth when the base is worn by the user wherein the wire is shaped to contact only one side of the tooth as required by independent Claim 58.

The '420 patent fails to disclose that the slot has a first portion, a second portion, a third portion and a fourth portion wherein the second portion is rearward in the mouth of the user with respect to the first portion wherein the third portion is rearward in the mouth of the user with respect to the second portion wherein the fourth portion is rearward in the mouth with respect to the third portion wherein the first portion is sized to receive an incisor type of tooth wherein the fourth portion is sized to receive a molar type of tooth of the user and further wherein the second portion and the third portion are shaped to contact teeth located between the incisor type of tooth and the molar type of tooth wherein the slot corrects a malocclusion of the teeth; continuously increasing the width of the slot from the first portion to the fourth portion; and forming wedges within the slot wherein the wedges extend outward with respect to the occlusal surface to form an apex which contacts the teeth as required by independent Claim 63.

The '420 patent fails to disclose contacting the canine type tooth with a wire embedded in the base wherein the wire extends from the base and contacts the canine type tooth only on one side of the canine type tooth as required by independent Claim 68.

The '420 patent fails to disclose forming wedges on the base and contacting an interproximal area of one of the teeth with the wedges wherein the interproximal area is located between adjacent

teeth and further wherein the wedge does not contact any area of the tooth other than the interproximal area wherein the wedge moves the tooth as required by independent Claim 74.

The '420 patent fails to disclose a first portion of the device having the socket wherein the first portion of the device is constructed from a first material; a second portion of the device constructed from a second material wherein the second portion of the device is different than the first portion of the device and the second material is harder than the first material; a rib on the flat occlusal surface wherein the rib is shaped to contact one or more of the teeth wherein the rib is positioned to contact an interproximal area of at least one tooth of the user when the base is worn by the user wherein the interproximal area is located between a first tooth and a second tooth and further wherein the rib guides one or more teeth of the user toward a position correcting a malocclusion of the teeth of the user when the base is worn by the user; and a wire embedded in the base wherein the wire extends from the socket and further wherein the wire extends from only one side of the socket as required by independent Claim 79.

The '420 patent fails to disclose a wire embedded in the base wherein the wire extends from the outer surface of one of the sockets wherein the wire contacts the first tooth and further wherein the wire extends from only one side of the socket as required by independent Claim 85.

Therefore, the '420 patent does not disclose the elements required by Claims 1, 8, 14, 35, 44, 58, 63, 68, 74, 79 and 85. Under 35 U.S.C. §102(b), anticipation requires that a single reference discloses each and every element of Appellant's claimed invention. *Akzo N.V. v. U.S. International Trade Commission*, 808 F.2d 1471, 1479, 1 USPQ 2d. 1241, 1245 (Fed. Cir. 1986). Moreover, anticipation is not shown even if the differences between the claims and the reference are "insubstantial", and one skilled in the art could supply the missing elements. *Structure Rubber Products Co. v. Park Rubber Co.*, 749 F.2d. 707, 716, 223 USPQ 1264, 1270 (Fed. Cir. 1984).

Further, Claims 85-87 are also rejected under 35 U.S.C. §103(a) as being unpatentable over the '420 patent, which demonstrates that the '420 patent lacks elements required by Claims 85-87.

Since the '420 patent fails to disclose the elements specifically defined in independent Claims 1, 8, 14, 35, 44, 58, 63, 68, 74, 79 and 85, Appellant asserts that the rejection of Claims 1-6, 8-12, 14, 16, 17, 19, 20, 35-39, 44-51, 58-66 and 68-87 under 35 U.S.C. §102(b) is improper and should be reversed.

**D. THE CITED REFERENCES AND REJECTIONS OF
CLAIMS 7, 13, 43, 52-57 and 85-87
UNDER 35 U.S.C. §103(a)**

Independent Claims 52 and 85 and dependent Claims 7, 13, 43, 53-57, 86 and 87 stand rejected under 35 U.S.C. §103(a) as being

unpatentable over the '420 patent.

**E. CLAIMS 7, 13, 43, 52-57 and 85-87 WOULD NOT
HAVE BEEN OBVIOUS UNDER 35 U.S.C. §103(a) TO
ONE OF ORDINARY SKILL IN THE ART
AT THE TIME OF APPELLANT'S INVENTION
IN VIEW OF THE CITED REFERENCE**

With respect to the rejection of Claims 7, 13, 43, 52-57 and 85-87 under 35 U.S.C. §103(a) as being unpatentable over the '420 patent, Appellant respectfully submits that the claims distinctly define the present invention from the '420 patent for the reasons that follow.

As discussed above, the '420 patent fails to teach what is alleged by the Examiner. The wire of the '420 patent is completely inside the appliance and does not contact a tooth. Further, the '420 patent merely teaches use of the second material as a liner on the interior of the first material to receive teeth based on their specific individual shapes. Still further, the '420 patent discloses troughs with sockets, not a slot that has an increased width rearward in the slot. Moreover, the alleged wedge in the '420 patent does not meet the limitations of the claimed wedge because element 22 does not extend from the socket or slot to contact only an interproximal area of teeth.

The '420 patent fails to teach or suggest a wire embedded within the base wherein the wire extends vertically from the base adjacent to the first side of the tooth and does not extend from the base adjacent to the second side of the tooth as required by

independent Claim 1 from which Claim 7 depends.

The '420 patent fails to teach or suggest forming wedges within the first socket wherein each of the wedges extend outward with respect to the occlusal surface of the first socket to form an apex shaped to extend toward a canine tooth that is one of the canine teeth and to contact the canine tooth wherein the wedges contact an interproximal area of the canine tooth wherein the interproximal area is located between the canine tooth and a second tooth and further wherein the wedge does not contact any area of the canine tooth other than the interproximal area; and moving the canine tooth with the wedge when the base is worn by the user as required by independent Claim 8 from which Claim 13 depends.

The '420 patent fails to teach or suggest a wire embedded within the base wherein the wire extends vertically from a top surface of the second wall toward the teeth when the base is worn by the user wherein the wire is shaped to contact a labial side of a first tooth wherein the first tooth is an incisor type tooth as required by independent Claim 35 from which Claim 43 depends.

The '420 patent fails to teach or suggest that the dental appliance is constructed from a first material and a second material wherein the first material is softer than the second material wherein a first portion of the dental appliance is constructed from the first material and contacts a first set of teeth and a second portion of the dental appliance is constructed

from a second material and contacts a second set of teeth wherein the first set of teeth and the second set of teeth are different sets of teeth wherein the dental appliance has a front end and further wherein the first portion is located in a first position relative to the front end and the second portion is located in a second position relative to the front end and the first position and the second position are different positions as required by independent Claim 52.

The '420 patent fails to teach or suggest a wire embedded in the base wherein the wire extends from the outer surface of one of the sockets wherein the wire contacts the first tooth and further wherein the wire extends from only one side of the socket as required by independent Claim 85.

With respect to the rejection of Claims 7, 13, 43, 52-57 and 85-87 under 35 U.S.C. §103(a) as being unpatentable over the '420 patent, the question is whether the totality of the art would collectively suggest the claimed invention to one of ordinary skill in the art. *In re Simon*, 461 F. 2d 1387, 174 USPQ 114 (CCPA 1972). That elements, even distinguishing elements, are disclosed in the art is insufficient. It is common to find elements somewhere in the art. The test is whether the invention as a whole, in light of the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 722 F. 2d

1542, 220 USPQ 193 (Fed. Cir. 1983).

With the analysis of the deficiencies of the '420 patent in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art would have been led to modify the '420 patent to produce the claimed inventions. Therefore, *prima facie* obviousness has not been established as required under 35 U.S.C. §103(a). Even assuming that one having ordinary skill in the art could have modified the cited reference, the reference still lacks the positively recited claim limitations. Accordingly, Appellant asserts that the rejection of Claims 7, 13, 43, 52-57 and 85-87 under 35 U.S.C. §103(a) as being unpatentable over the '420 patent is improper and should be reversed.

**F. THE CITED REFERENCES AND REJECTIONS OF
CLAIMS 15, 40 AND 67 UNDER 35 U.S.C. §103(a)**

Dependent Claims 15, 40 and 67 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view of *Andrews*.

**G. CLAIMS 15, 40 AND 67 WOULD NOT HAVE BEEN OBVIOUS
UNDER 35 U.S.C. §103(a)
TO ONE OF ORDINARY SKILL IN THE ART AT THE TIME OF
APPELLANT'S INVENTION IN VIEW OF THE CITED REFERENCES,
TAKEN SINGLY OR IN COMBINATION**

With respect to the rejection of Claims 15, 40 and 67 under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view of *Andrews*, Appellant respectfully submits that the claims distinctly define the present invention from the '420 patent in

view of *Andrews*, taken singly or in combination, for the reasons that follow.

As discussed above, the '420 patent fails to teach what is alleged by the Examiner. The wire of the '420 patent is completely inside the appliance and does not contact a tooth. Further, the '420 patent merely teaches use of the second material as a liner on the interior of the first material to receive teeth based on their specific individual shapes. Still further, the '420 patent discloses troughs with sockets, not a slot that has an increased width rearward in the slot. Moreover, the alleged wedge in the '420 patent does not meet the limitations of the claimed wedge because element 22 does not extend from the socket or slot to contact only an interproximal area of teeth.

Andrews does not remedy the deficiencies of the '420 patent with respect to the claimed invention. *Andrews* merely teaches an orthodontic positioner with suction devices attached to interior walls of the positioner.

Nowhere do the '420 patent or *Andrews*, taken singly or in combination, teach or suggest applying pressure to one side of the first tooth with a wire embedded within the base wherein the wire extends vertically from the base and contacts the first tooth only on the one side of the first tooth as required by independent Claim 14 from which Claim 15 depends.

Nowhere do the '420 patent or *Andrews*, taken singly or in

combination, teach or suggest a wire embedded within the base wherein the wire extends vertically from a top surface of the second wall toward the teeth when the base is worn by the user wherein the wire is shaped to contact a labial side of a first tooth wherein the first tooth is an incisor type tooth as required by independent Claim 35 from which Claim 40 depends.

Nowhere do the '420 patent or *Andrews*, taken singly or in combination, teach or suggest that the slot has a first portion, a second portion, a third portion and a fourth portion wherein the second portion is rearward in the mouth of the user with respect to the first portion wherein the third portion is rearward in the mouth of the user with respect to the second portion wherein the fourth portion is rearward in the mouth with respect to the third portion wherein the first portion is sized to receive an incisor type of tooth wherein the fourth portion is sized to receive a molar type of tooth of the user and further wherein the second portion and the third portion are shaped to contact teeth located between the incisor type of tooth and the molar type of tooth wherein the slot corrects a malocclusion of the teeth; continuously increasing the width of the slot from the first portion to the fourth portion; and forming wedges within the slot wherein the wedges extend outward with respect to the occlusal surface to form an apex which contacts the teeth as required by independent Claim 63 from which Claim 67 depends.

With respect to the rejection of Claims 15, 40 and 67 under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view of *Andrews*, the question is whether the totality of the art would collectively suggest the claimed invention to one of ordinary skill in the art. *In re Simon*, 461 F. 2d 1387, 174 USPQ 114 (CCPA 1972). That elements, even distinguishing elements, are disclosed in the art is insufficient. It is common to find elements somewhere in the art. The test is whether the invention as a whole, in light of the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 722 F. 2d 1542, 220 USPQ 193 (Fed. Cir. 1983).

With the analysis of the deficiencies of the '420 patent and *Andrews* in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art would have been led to combine the '420 patent and *Andrews* to produce the claimed inventions. Therefore, *prima facie* obviousness has not been established as required under 35 U.S.C. §103(a). Even assuming that one having ordinary skill in the art could have combined the cited references by the Patent Office, the references still lack the positively recited claim limitations. Accordingly, Appellant asserts that the rejection of Claims 15, 40 and 67 under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view of *Andrews* is improper and should be reversed.

**H. THE CITED REFERENCES AND REJECTIONS OF
CLAIMS 6, 42 and 66 UNDER 35 U.S.C. §103(a)**

Dependent Claims 6, 42 and 66 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view of *Watson et al.*

**I. CLAIMS 6, 42 and 66 WOULD NOT HAVE BEEN OBVIOUS
UNDER 35 U.S.C. §103(a)
TO ONE OF ORDINARY SKILL IN THE ART AT THE TIME OF
APPELLANT'S INVENTION IN VIEW OF THE CITED REFERENCES,
TAKEN SINGLY OR IN COMBINATION**

With respect to the rejection of Claims 6, 42 and 66 under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view of *Watson et al.*, Appellant respectfully submits that the claims distinctly define the present invention from the '420 patent in view of *Watson et al.*, taken singly or in combination, for the reasons that follow.

As discussed above, the '420 patent fails to teach what is alleged by the Examiner. The wire of the '420 patent is completely inside the appliance and does not contact a tooth. Further, the '420 patent merely teaches use of the second material as a liner on the interior of the first material to receive teeth based on their specific individual shapes. Still further, the '420 patent discloses troughs with sockets, not a slot that has an increased width rearward in the slot. Moreover, the alleged wedge in the '420 patent does not meet the limitations of the claimed wedge because element 22 does not extend from the socket or slot to contact only an interproximal area of teeth.

Watson et al. do not remedy the deficiencies of the '420 patent with respect to the claimed invention. On the contrary, *Watson et al.* merely teach a unitary plural-material, interocclusal dental appliance for use in connection with orthodontic/orthopedic treatment of the teeth and jaws of a mouth of a patient. The appliance has a first layer made from a first material that provides a relatively hard expanse with first and second surfaces with the second surface contacting the teeth. A second layer is joined to the first layer and is made from a second material that provides a relatively soft, persistently resilient enclosure. The first layer and the second layer of the appliance of *Watson et al.* do not contact separate sets of teeth.

Nowhere do the '420 patent or *Watson et al.*, taken singly or in combination, teach or suggest as required by independent Claim 1 from which Claim 6 depends.

Nowhere do the '420 patent or *Watson et al.*, taken singly or in combination, teach or suggest a wire embedded within the base wherein the wire extends vertically from a top surface of the second wall toward the teeth when the base is worn by the user wherein the wire is shaped to contact a labial side of a first tooth wherein the first tooth is an incisor type tooth as required by independent Claim 35 from which Claim 42 depends.

Nowhere do the '420 patent or *Watson et al.*, taken singly or in combination, teach or suggest that the slot has a first portion,

a second portion, a third portion and a fourth portion wherein the second portion is rearward in the mouth of the user with respect to the first portion wherein the third portion is rearward in the mouth of the user with respect to the second portion wherein the fourth portion is rearward in the mouth with respect to the third portion wherein the first portion is sized to receive an incisor type of tooth wherein the fourth portion is sized to receive a molar type of tooth of the user and further wherein the second portion and the third portion are shaped to contact teeth located between the incisor type of tooth and the molar type of tooth wherein the slot corrects a malocclusion of the teeth; continuously increasing the width of the slot from the first portion to the fourth portion; and forming wedges within the slot wherein the wedges extend outward with respect to the occlusal surface to form an apex which contacts the teeth as required by independent Claim 63 from which Claim 66 depends.

With respect to the rejection of Claims 15, 40 and 67 under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view of *Watson et al.*, the question is whether the totality of the art would collectively suggest the claimed invention to one of ordinary skill in the art. *In re Simon*, 461 F. 2d 1387, 174 USPQ 114 (CCPA 1972). That elements, even distinguishing elements, are disclosed in the art is insufficient. It is common to find elements somewhere in the art. The test is whether the invention as a

whole, in light of the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made. *Connell v. Sears, Roebuck & Co.*, 722 F. 2d 1542, 220 USPQ 193 (Fed. Cir. 1983).

With the analysis of the deficiencies of the '420 patent and *Watson et al.* in mind, as enumerated above, no reason or suggestion in the evidence of record exists why one of ordinary skill in the art would have been led to combine the '420 patent and *Watson et al.* to produce the claimed inventions. Therefore, *prima facie* obviousness has not been established as required under 35 U.S.C. §103(a). Even assuming that one having ordinary skill in the art could have combined the cited references by the Patent Office, the references still lack the positively recited claim limitations. Accordingly, Appellant asserts that the rejection of Claims 6, 42 and 66 under 35 U.S.C. §103(a) as being unpatentable over the '420 patent in view of *Watson et al.* is improper and should be reversed.

VIII. CONCLUSION

For the foregoing reasons, Appellant respectfully submits that the rejection of Claims 1-20 and 35-87 is erroneous as a matter of law and fact and respectfully requests the Board to reverse the rejections.

Respectfully submitted,

(Reg. No. 35,018)

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1. CLAIMS APPENDIX

Claims 1-20 and 35-87

2. SUPPLEMENTAL APPENDIX

EXHIBIT A: Final Rejection dated November 28, 2007

EXHIBIT B: U.S. Patent No. 5,645,420 to *Bergersen*

EXHIBIT C: U.S. Patent No. 4,591,341 to *Andrews*

EXHIBIT D: U.S. Patent No. 5,328,362 to *Watson et al.*

3. EVIDENCE APPENDIX

NONE

4. RELATED PROCEEDINGS APPENDIX

NONE



CLAIMS APPENDIX

Claim 1: A dental appliance adapted to be worn in a mouth of a user having one or more types of teeth, the dental appliance comprising:

a generally U-shaped base having a flat occlusal surface wherein the flat occlusal surface is shaped to contact the teeth wherein the base is preformed and has a length defined between a first end and a second end;

a first wall extending from the flat surface wherein the first wall defines an interior surface;

a second wall extending from the flat surface wherein the second wall defines an exterior surface;

a wire embedded within the base wherein one of the teeth has a first side and a second side wherein the second side is positioned opposite to the first side wherein the wire extends vertically from the base adjacent to the first side of the tooth and does not extend from the base adjacent to the second side of the tooth; and

a slot in the base wherein the slot is defined between the first wall and the second wall wherein the slot extends along the length of the base from the first end of the base to the second end of the base wherein the slot defines a width of the flat occlusal surface wherein the width of the slot increases from a first portion of the slot to a second portion of the slot wherein the first portion of the slot is shaped to contact a front of the mouth wherein the second portion of the slot is shaped to extend rearward in the mouth and further wherein the second portion of the

slot is sized to receive canine type of teeth of the user wherein the second portion of the slot is shaped to move the canine type of teeth when the base is worn by the user wherein the second portion of the slot is shaped to correct the malocclusion of the canine type teeth.

Claim 2: The dental appliance of Claim 1 wherein the first portion is sized to receive an incisor type of tooth.

Claim 3: The dental appliance of Claim 1 wherein the first portion of the slot is sized to receive teeth which are located toward a front of the mouth with respect to the canine type teeth of the user.

Claim 4: The dental appliance of Claim 1 further comprising:

lingual tabs formed within the interior surface wherein the lingual tabs are positioned to extend rearward into the mouth of the user when the base is worn by the user.

Claim 5: The dental appliance of Claim 1 wherein the embedded wire extends from the second wall.

Claim 6: The dental appliance of Claim 1 wherein the base is constructed from a first material and a second material wherein the first material is softer than the second material wherein the second portion of the slot is constructed from the first material and the first portion of the slot is constructed from the second material.

Claim 7: The dental appliance of Claim 1 wherein the embedded wire extends from the first wall.

Claim 8: A method for correcting a dentition in a mouth of a user having one or more types of teeth wherein one of the types of teeth is canine teeth, the method comprising the steps of:

providing a generally U-shaped base having a first socket that receives the canine teeth ;

contacting the canine teeth with the generally U-shaped base wherein the generally U-shaped base contacts the canine teeth on an outer side of the canine teeth and on an inner side of the canine teeth wherein the inner side of the canine teeth is opposite in position to the outer side wherein the socket has an occlusal surface;

forming wedges within the first socket wherein each of the wedges extend outward with respect to the occlusal surface of the first socket to form an apex shaped to extend toward a canine tooth that is one of the canine teeth and to contact the canine tooth wherein the wedges contact an interproximal area of the canine tooth wherein the interproximal area is located between the canine tooth and a second tooth and further wherein the wedge does not contact any area of the canine tooth other than the interproximal area; and

moving the canine tooth with the wedge when the base is worn by the user.

Claim 9: The method of Claim 8 further comprising the step of:

attaching a second base to the U-shaped base wherein the second base has an occlusal surface.

Claim 10: The method of Claim 8 further comprising the step of:

forming a second socket shaped to receive a second type of teeth wherein the type is not canine teeth.

Claim 11: The method of Claim 8 further comprising the steps of:

forming a first area which is shaped to receive a first type of teeth; and

forming a second area which is shaped to receive a second type of teeth wherein the first area is a greater thickness than the second area.

Claim 12: The method of Claim 8 further comprising the step of:

applying pressure to one side of a tooth with a wire embedded within the base wherein the wire does not contact a second side of the tooth wherein the second side of the tooth is positioned opposite to the first side of the tooth.

Claim 13: The method of Claim 8 further comprising the step of:

contacting at least one of the teeth with the base but not contacting all of the teeth with the base.

Claim 14: A method for correcting a dentition in a mouth of a user having teeth, the method comprising the steps of:

a generally U-shaped base;

sockets within the base wherein at least one of the sockets is preformed wherein at least one of the sockets has peripheral walls defining an interior wherein the interior is shaped to receive a first tooth wherein the peripheral walls separate a first tooth from a second tooth wherein the sockets are shaped to treat a

malocclusion; and

applying pressure to one side of the first tooth with a wire embedded within the base wherein the wire extends vertically from the base and contacts the first tooth only on the one side of the first tooth.

Claim 15: The method of Claim 14 further comprising the step of:
attaching a suction cup to the base.

Claim 16: The method of Claim 14 wherein the sockets are preformed.

Claim 17: The method of Claim 14 further comprising the step of:
customizing at least one of the sockets.

Claim 18: The method of Claim 14 wherein the one side of the first tooth is a lingual side that is adjacent to a tongue of the user.

Claim 19: The method of Claim 14 wherein the one side of the first tooth is a labio-buccal side that is adjacent to lips of the user.

Claim 20: The method of Claim 14 further comprising the step of:
attaching a liner to the base wherein the liner has a surface which is shaped to contact the mouth to prevent the base from moving within the mouth when the base is worn by the user.

Claim 35: A dental appliance adapted to be worn in a mouth of a user having teeth, the dental appliance comprising:

a generally U-shaped base having an occlusal surface wherein the occlusal surface contacts the teeth when the dental appliance is worn by the user;

a first wall extending from the occlusal surface wherein the

first wall defines an interior surface;

a second wall extending from the occlusal surface wherein the second wall defines an exterior surface and wherein the first wall and the second wall define a width of the occlusal surface;

a liquid within the generally U-shaped base wherein the liquid is released from the generally U-shaped base; and

a wire embedded within the base wherein the wire extends vertically from a top surface of the second wall toward the teeth when the base is worn by the user wherein the wire is shaped to contact a labial side of a first tooth wherein the first tooth is an incisor type tooth.

Claim 36: The dental appliance of Claim 35 further comprising:

a first socket within the occlusal surface having a first size; and

a second socket within the occlusal surface having a second size wherein the first size and the second size are different.

Claim 37: The dental appliance of Claim 35 further comprising:

a labial shield extending from the second wall wherein the labial shield is shaped to cover the teeth.

Claim 38: The dental appliance of Claim 35 further comprising:

lingual tabs extending from the first wall wherein the lingual tabs extend into the mouth when the dental appliance is worn by the user.

Claim 39: The dental appliance of Claim 35 wherein the liquid has fluoride.

Claim 40: The dental appliance of Claim 35 further comprising:
suction cups extending from the occlusal surface.

Claim 41: The dental appliance of Claim 35 further comprising:
a reline material on the occlusal surface.

Claim 42: The dental appliance of Claim 35 wherein the base is constructed from a first material and a second material wherein the first material is softer than the second material wherein a portion of the base that contacts the first tooth is constructed from the first material and a portion of the base that does not contact the first tooth is constructed from the second material.

Claim 43: The dental appliance of Claim 35 further comprising:
a vertical slit on the exterior surface.

Claim 44: A dental appliance adapted to be worn in a mouth of a user having one or more types of teeth, the dental appliance comprising:

a generally U-shaped base having a flat occlusal surface wherein the occlusal surface is shaped to contact the teeth; ~~and~~

at least one socket within the occlusal surface wherein each socket has a first wall and a second wall wherein the second wall separates a first tooth from a second tooth wherein the socket is sized based on anatomical standards for teeth wherein at least one socket is shaped to receive canine type teeth regardless of anatomical variations of the canine type teeth of the user; and

a wire embedded within the base wherein the wire is shaped to contact only a labial side of one of the teeth.

Claim 45: The dental appliance of Claim 44 wherein the socket is sized to receive two or more teeth.

Claim 46: The dental appliance of Claim 44 wherein the socket is sized to receive one tooth.

Claim 47: The dental appliance of Claim 44 further comprising:

lingual tabs extending from the base wherein the lingual tabs extend rearward into the mouth when the base is worn by the user.

Claim 48: The dental appliance of Claim 44 wherein the flat occlusal surface is sized to receive two or more teeth.

Claim 49: The dental appliance of Claim 44 further comprising:

fluoride within the generally U-shaped base.

Claim 50: The dental appliance of Claim 44 further comprising:

a liner on the base wherein the liner is adapted to cause adhesion between the base and the teeth.

Claim 51: The dental appliance of Claim 44 further comprising:

a labial shield extending from the second wall wherein the labial shield is shaped to cover the teeth.

Claim 52: A method for diagnosing an orthodontic condition of a patient, the method comprising the steps of:

providing an analysis means for the patient to analyze a position of one or more teeth within a mouth of the patient wherein a width of the mouth is measured by the analysis means;

displaying a tooth arrangement to which the patient compares the position of the one or more teeth; and

distributing a dental appliance to the patient after the

patient compares the position of the one or more teeth wherein a size of the dental appliance corresponds to the width of the mouth wherein the dental appliance is constructed from a first material and a second material wherein the first material is softer than the second material wherein a first portion of the dental appliance is constructed from the first material and contacts a first set of teeth and a second portion of the dental appliance is constructed from a second material and contacts a second set of teeth wherein the first set of teeth and the second set of teeth are different sets of teeth wherein the dental appliance has a front end and further wherein the first portion is located in a first position relative to the front end and the second portion is located in a second position relative to the front end and the first position and the second position are different positions.

Claim 53: The method of Claim 52 further comprising the step of:
creating the dental appliance based on a digital model of the teeth within the mouth.

Claim 54: The method of Claim 52 wherein the analysis means is a ruler.

Claim 55: The method of Claim 52 wherein the analysis means is a mirror.

Claim 56: The method of Claim 52 wherein the analysis means is a packaging displaying an image of teeth.

Claim 57: The method of Claim 52 wherein the analysis means is a camera.

Claim 58: A dental appliance adapted to be worn in a mouth of a user having teeth wherein a first tooth is a canine tooth, the dental appliance comprising:

a generally U-shaped base having an occlusal surface which is shaped to contact the teeth when the base is worn by the user wherein the occlusal surface has a first area wherein the first area is sized to receive the canine tooth wherein the first area is shaped to receive the canine teeth regardless of anatomical variations of canine type teeth of the user wherein the generally U-shaped base has an exterior surface;

an incisal edge within the first area of the occlusal surface wherein the incisal edge inclines outward with respect to the occlusal surface and wherein the incisal edge is sized to contact the canine tooth and further wherein the incisal edge is shaped to move the canine tooth wherein the incisal edge is shaped to prevent a malocclusion of the teeth of the user wherein a first portion of the device is constructed from a first material and contacts a first set of teeth and a second portion of the device is constructed from a second material that is softer than the first material and contacts a second set of teeth wherein the second portion of the device has the incisal edge wherein the first set of teeth and the second set of teeth are different sets of teeth; and

a wire embedded within the base wherein the wire extends vertically from the exterior surface of the generally U-shaped base toward a tooth when the base is worn by the user wherein the wire

is shaped to contact only one side of the tooth.

Claim 59: The dental appliance of Claim 58 further comprising:

a second base attached to the U-shaped base wherein the second base has an occlusal surface.

Claim 60: The dental appliance of Claim 58 further comprising:

one or more sockets wherein the sockets are shaped to receive a second tooth wherein the second tooth is not a canine tooth.

Claim 61: The dental appliance of Claim 58 wherein the wire embedded within the base contacts a labial side of the tooth.

Claim 62: The dental appliance of Claim 58 wherein the occlusal surface has a second area shaped to receive a second tooth wherein the second tooth is not a canine tooth.

Claim 63: A method for treating a malocclusion in a mouth of a user having one or more types of teeth, the method comprising the steps of:

designing a generally U-shaped base having a flat occlusal surface wherein the flat occlusal surface is shaped to contact the teeth of the user wherein the base has a length defined between a first end and a second end;

forming a first wall extending from the flat surface wherein the first wall defines an interior surface;

forming a second wall extending from the flat surface wherein the second wall defines an exterior surface;

forming a slot in the base wherein the slot is located between the first wall and the second wall wherein the slot extends along the length of the base from the first end of the base to the second

end of the base wherein the slot defines a width of the flat occlusal surface wherein the slot has a first portion, a second portion, a third portion and a fourth portion wherein the second portion is rearward in the mouth of the user with respect to the first portion wherein the third portion is rearward in the mouth of the user with respect to the second portion wherein the fourth portion is rearward in the mouth with respect to the third portion wherein the first portion is sized to receive an incisor type of tooth wherein the fourth portion is sized to receive a molar type of tooth of the user and further wherein the second portion and the third portion are shaped to contact teeth located between the incisor type of tooth and the molar type of tooth wherein the slot corrects a malocclusion of the teeth;

continuously increasing the width of the slot from the first portion to the fourth portion; and

forming wedges within the slot wherein the wedges extend outward with respect to the occlusal surface to form an apex which contacts the teeth.

Claim 64: The method of Claim 63 further comprising the step of:

forming lingual tabs within the interior surface wherein the lingual tabs are positioned to extend rearward into the mouth of the user when the dental appliance is worn by the user.

Claim 65: The method of Claim 63 further comprising the step of:

constructing the base from a moisture-absorbent material.

Claim 66: The method of Claim 63 further comprising the step of:

constructing the base from a first material and a second

material wherein the first material is softer than the second material wherein a first section of the slot is constructed from the first material and a second section of the slot is constructed of the second material wherein the first section contacts different teeth than the second section.

Claim 67: The method of Claim 63 further comprising the step of::
forming suction cups on the base.

Claim 68: A method for treating a malocclusion in a mouth of a user having one or more types of teeth, the method comprising the steps of:

designing a generally U-shaped base having a flat occlusal surface wherein the flat occlusal surface is shaped to contact the teeth and further wherein the base is preformed;

forming a first pre-formed socket and a second pre-formed socket within the flat occlusal surface wherein the first socket is sized to receive a canine type tooth wherein the second socket is shaped to receive at least one of the teeth which is not the canine type of teeth of the user;

separating the canine type tooth from teeth which are not the canine type of teeth wherein the first socket separates the canine type tooth from teeth which are not the canine type of teeth wherein the first socket moves the canine type tooth with respect to the teeth when the base is worn by the user; and

contacting the canine type tooth with a wire embedded in the base wherein the wire extends from the base and contacts the canine type tooth only on one side of the canine type tooth.

Claim 69: The method of Claim 68 further comprising the step of:
sizing the second socket to receive two or more teeth of the user.

Claim 70: The method of Claim 68 further comprising the step of:
customizing the second socket to receive at least one of the teeth which is not the canine type teeth of the user.

Claim 71: The method of Claim 68 further comprising the step of:
forming lingual tabs extending from the base wherein the lingual tabs extend rearward into the mouth when the base is worn by the user.

Claim 72: The method of Claim 68 further comprising the step of:
extending the wire into the first socket.

Claim 73: The method of Claim 68 further comprising the step of:
attaching a liner to the base wherein the liner adheres the base to the teeth of the user when the dental appliance is worn by the user.

Claim 74: A method for correcting a malocclusion in a mouth of a user having teeth, the method comprising the steps of:

providing a generally U-shaped base;
forming sockets within the base wherein one of the sockets receives at least one of the teeth of the user wherein at least one of the sockets is sized to receive a canine type tooth and separates the canine type tooth from the teeth of the user which are not canine type teeth;

shaping the socket to move the canine type tooth from a first position to a second position wherein the second position is closer

to a front of the mouth of the user than the first position when the base is worn by the user;

attaching a liner in one of the sockets wherein the liner has a thickness defined between a top surface and a bottom surface wherein the bottom surface of the liner attaches to at least one of the sockets wherein the top surface of the liner contacts the teeth when the base is worn by the user wherein the liner is shaped to contact the teeth and wherein the liner prevents movement of the base away from the teeth when the base is worn in the mouth of the user;

forming wedges on the base; and

contacting an interproximal area of one of the teeth with the wedges wherein the interproximal area is located between adjacent teeth and further wherein the wedge does not contact any area of the tooth other than the interproximal area wherein the wedge moves the tooth.

Claim 75: The method of Claim 74 further comprising the step of:

customizing one of the sockets to receive at least one of the teeth of the user.

Claim 76: The method of Claim 74 wherein the base is preformed.

Claim 77: The method of Claim 74 further comprising the step of:

contacting a tooth with a wire embedded in the base wherein the wire extends from the base and contacts the tooth only on one side of the tooth wherein the wire moves the tooth.

Claim 78: The method of Claim 74 wherein one of the sockets is flat.

Claim 79: A dental appliance adapted to be worn in a mouth of a user having one or more types of teeth, the dental appliance comprising:

- a generally U-shaped base having a flat occlusal surface wherein the flat occlusal surface contacts the teeth when the base is worn by the user;

- a socket within the flat occlusal surface wherein the socket is shaped to receive one or more of the teeth of the user;

- a first portion of the device having the socket wherein the first portion of the device is constructed from a first material;

- a second portion of the device constructed from a second material wherein the second portion of the device is different than the first portion of the device and the second material is harder than the first material;

- a rib on the flat occlusal surface wherein the rib is shaped to contact one or more of the teeth wherein the rib is positioned to contact an interproximal area of at least one tooth of the user when the base is worn by the user wherein the interproximal area is located between a first tooth and a second tooth and further wherein the rib guides one or more teeth of the user toward a position correcting a malocclusion of the teeth of the user when the base is worn by the user; and

- a wire embedded in the base wherein the wire extends from the socket and further wherein the wire extends from only one side of the socket.

Claim 80: The dental appliance of Claim 79 wherein the base is

preformed.

Claim 81: The dental appliance of Claim 79 wherein the socket is customized to receive one or more teeth of the user.

Claim 82: The dental appliance of Claim 79 further comprising:

lingual tabs extending from the base wherein the lingual tabs extend rearward into the mouth when the base is worn by the user.

Claim 83: The dental appliance of Claim 79 wherein the wire embedded within the base extends from a labial side of the socket.

Claim 84: The dental appliance of Claim 79 further comprising:

a liner on the base wherein the liner causes adhesion between the base and the teeth of the user when the dental appliance is worn by the user.

Claim 85: A dental appliance adapted to be worn in a mouth of a user having one or more types of teeth, the dental appliance comprising:

a generally U-shaped base having a flat occlusal surface wherein the flat occlusal surface is shaped to contact the teeth of the user wherein the base is preformed and designed from a digital model by a computer wherein the base is sized to correspond to the digital model wherein the digital model corresponds to the teeth of the user;

sockets within the flat occlusal surface wherein the sockets have outer surfaces wherein one of the sockets is sized to receive one or more teeth of the user wherein at least one of the sockets separates a first tooth from a second tooth wherein at least one of the sockets is sized to receive a canine type tooth and to move the

canine type tooth with respect to the teeth when the base is worn by the user; and

a wire embedded in the base wherein the wire extends from the outer surface of one of the sockets wherein the wire contacts the first tooth and further wherein the wire extends from only one side of the socket.

Claim 86: The dental appliance of Claim 85 wherein the base is molded from a computer program.

Claim 87: The dental appliance of Claim 85 wherein the base is molded by a vacuum, a pressure type device or stereolithography.



SUPPLEMENTAL APPENDIX

EXHIBIT A



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,441	09/18/2003	Earl O. Bergersen	BER-P-03-054	7298
29013	7590	12/28/2007		
PATENTS+TMS, P.C. 2849 W. ARMITAGE AVE. CHICAGO, IL 60647			EXAMINER LEWIS, RALPH A	
			ART UNIT 3732	PAPER NUMBER
			MAIL DATE 12/28/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,441	BERGERSEN, EARL O.	
	Examiner	Art Unit	
	Ralph A. Lewis	3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-87 is/are pending in the application.
- 4a) Of the above claim(s) 21-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 and 35-87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election by Original Presentation

Newly amended claims 21-34 are directed to an invention that is independent or distinct from the invention originally claimed because they are directed to a method of sequentially using different sized appliances to treat a patient whereas the remaining claims are directed to particular embodiments of an appliance. The method could be performed by appliances other than the embodiments claimed and the embodiments claimed can be used in methods other than a sequential method where different sized appliances are used on a patient over time.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Obvious-Type Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 and 35-87 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over

Claims 1-110 of copending Application No. 10/447,099;

Claims 1-114 of copending Application No. 10/449,292;

Claims 1-139 of copending Application No. 10/449,312;

Claims 1-82 of copending Application No. 10/760,604; and

Claims 1-51 of copending Application No. 11/257,330

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the present application are merely obvious variations of the claims presented in applicant's other applications. Merely rearranging the order of claimed elements and using different wording to refer to the same subject matter would have been obvious to the ordinarily skilled artisan.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Rejections based on Prior Art

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-12, 14, 16, 17, 19, 20, 35-39, 44-51, 58-66 and 68-87 are rejected under 35 U.S.C. 102(b) as being anticipated by Bergersen (US 5,645,420).

Bergersen '420 discloses a dental appliance having a general U-shaped base (Figure 2), flat occlusal surface 50 (note Fig 5), first wall 26, second wall 28, slot 22 whose width increases from the front (Figure 3) to the rear (Figure 5). In regard to the newly added limitation of claim 1 that there is a wire embedded in the base and extending vertically from the base along one side of a tooth, applicant's attention is drawn to Figures 13 and 14 of Bergersen '420 where such a feature is clearly shown. In regard to claim 4, note lingual tabs 34. In regard to claim 6, note column 8, lines 1-22. In regard to claim 8, note wedges 22 (Figure 3). In regard to claim 9, note Fig 15. In regard to claims 35 and 39, note column 11, lines 5-12, regarding the delivery of fluoride. Additionally, in regard to claims 41 and 42, Bergersen '420 discloses a second portion 60 of the device which is made of a softer material and which contacts a second set of teeth which is different from the first set of teeth which are not contacted by the softer material 60. In regard to claims 35 and 39, note column 11, lines 5-12, regarding the delivery of fluoride.

In response to the rejection of claim 1, applicant added the further limitation that the dental appliance has a wire embedded in the base that extends vertically from the base adjacent only one side of a tooth. Applicant's earlier '420 patent has an embedded wire 104 to "assist in maintaining the desired buccal expansion dimension or other configuration of the appliance" (column 10, lines 4-10) that in Figures 13 and 14 is clearly illustrated as extending vertically adjacent one side of a tooth.

In response to the rejection of claims 35 and 39, applicant further added the limitation regarding the addition of fluoride to the device which was also clearly disclosed in applicant's earlier patent ten years ago.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 13, 43, 52-57 and 85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen (US 5,645,420).

In regard to claims 7, 18, Bergersen discloses the wire 104 embedded in an external wall rather than the internal wall as claimed. One of ordinary skill in the art, however, would have found it obvious to have embedded the wire in the internal wall of the appliance in order to push the inner side of the patient's teeth. In regard to claim 13,

constructing the appliance so that it does not touch the occlusal surface of every tooth (e.g. a tooth that is not fully erupted) would have been obvious as a matter of routine practice. In regard to claim 43, the inclusion of a conventional slit in the Bergersen appliance in order to increase flexibility would have been obvious to one of ordinary skill in the art. In regard to claim 52-57, it would have been obvious for the practitioner to explain to the patient using convention methods what procedure was being under taken.

Claims 15, 40 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen (US 5,645,420) in view of Andrews (US 4,591,341).

Andrews teaches the use of small suction cups (14, 16, 20, 24, 26, 30) positioned in an orthodontic appliance in order to provide increased adherence and firmly hold the teeth together in the desired position. To have provided the Bergersen orthodontic appliance with small suction cups in order to provide increased adherence and firmly hold the teeth together in the desired position as taught by Andrews would have been obvious to one of ordinary skill in the art.

Claims 6, 42 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bergersen (US 5,645,420) in view of Watson et al (US 5,328,362).

Watson et al teach the construction of dental appliances of a first relatively rigid material and a second relatively soft resilient material for aiding in the proper movement of the patient's teeth. To have constructed the Bergersen orthodontic appliance of hard

and soft materials as taught by Watson et al in order to aid in the proper movement of the patient's teeth would have been obvious to one of ordinary skill in the art.

Action Made Final

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication should be directed to **Ralph Lewis** at telephone number **(571) 272-4712**. Fax (571) 273-8300. The examiner works a compressed work schedule and is unavailable every other Friday. The examiner's supervisor, Cris Rodriguez, can be reached at (571) 272-4964.

R.Lewis
December 26, 2007

/Ralph Lewis/
Primary Examiner
Art Unit 3732

EXHIBIT B



US005645420A

United States Patent [19]**Bergersen**[11] **Patent Number:** **5,645,420**[45] **Date of Patent:** **Jul. 8, 1997**[54] **MULTI-RACIAL PREFORMED
ORTHODONTIC TREATMENT APPLICANCE**[75] **Inventor:** Earl O. Bergersen, Winnetka, Ill.[73] **Assignee:** Ortho-Tain, Inc., Bayamon, Puerto Rico[21] **Appl. No.:** 407,919[22] **Filed:** Mar. 21, 1995**Related U.S. Application Data**

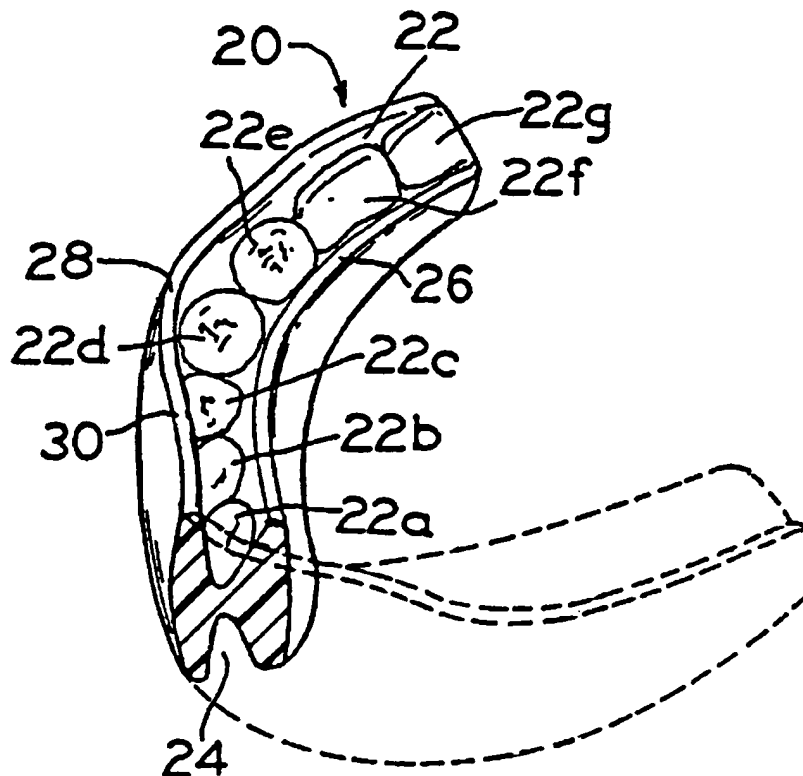
[63] Continuation of Ser. No. 89,577, Jul. 12, 1993, abandoned.

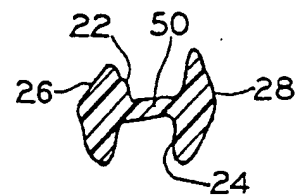
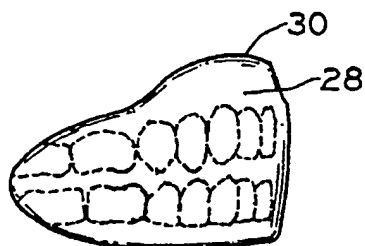
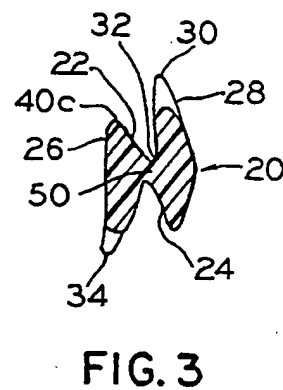
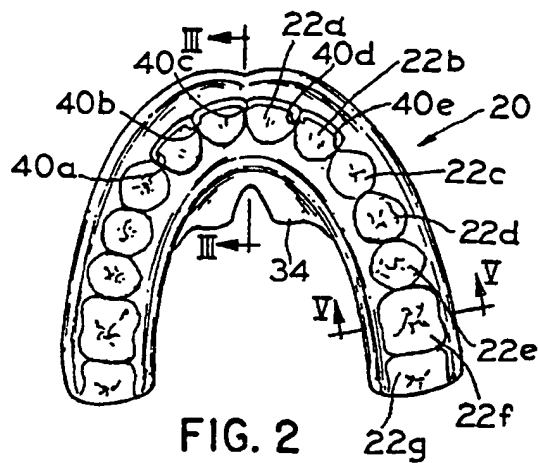
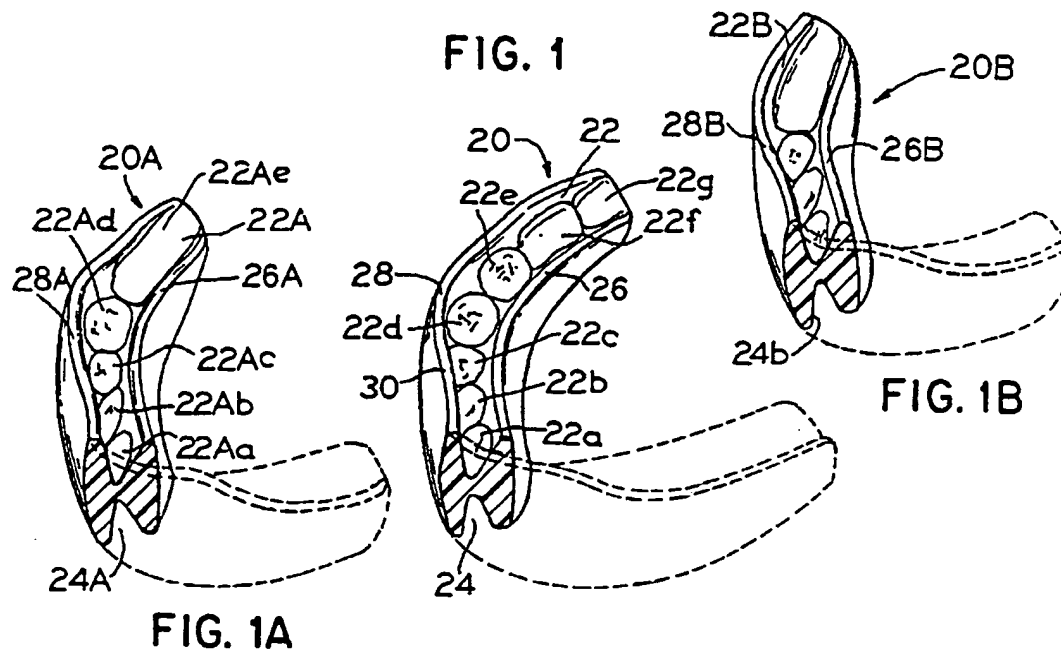
[51] **Int. Cl.⁶** A61C 3/00[52] **U.S. Cl.** 433/6[58] **Field of Search** 433/6, 24; 128/861[56] **References Cited****U.S. PATENT DOCUMENTS**

3,478,429	11/1969	Shilliday	433/6
4,504,225	3/1985	Yoshii	433/6
5,028,231	7/1991	Hall	433/6
5,059,118	10/1991	Breads et al.	433/6
5,259,762	11/1993	Farrell	433/6 X

Primary Examiner—Nicholas D. Lucchesi*Attorney, Agent, or Firm*—Hill, Steadman & Simpson[57] **ABSTRACT**

An orthodontic appliance of the type which is generally U-shaped in plan view and includes a tooth receiving trough formed between lingual and labial/buccal side flanges in at least one of the upper or lower sides thereof is provided for use by Caucasoid, Mongoloid and Negroid patients. The trough includes tooth receiving depressions for receiving and positioning teeth from central and lateral incisors to and including a molar. The appliance preferably is preformed in a range of different sizes to accommodate different sized mouths and stages of dentition. The troughs, when two are provided, may be vertically fixed relative to one another in that the appliance is a single body device or may be movable relative to one another and joined at a pair of posterior hinges. The labial flange, in an area of the incisors, extends gingivally from a tooth receiving surface of said trough by more than 10 mm so as to overlie a patient's gingival labial tissue and pre-maxilla to an extent not previously provided and up to 10 mm further gingivally on the lingual in the area of the four lower incisors. Further, the lingual flange defining the upper trough has lingually extending depressions of 0.1 to 1 mm which extend slightly laterally at a mesial area and distal edge of the central incisors and at a distal edge and a mesial edge of the lateral incisors so as to be positioned adjacent to the lateral edges of all four incisors.

36 Claims, 2 Drawing Sheets



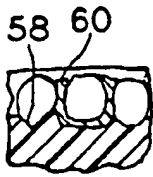


FIG. 6

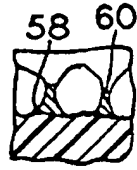


FIG. 7

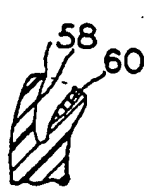


FIG. 8

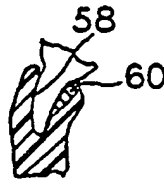


FIG. 9

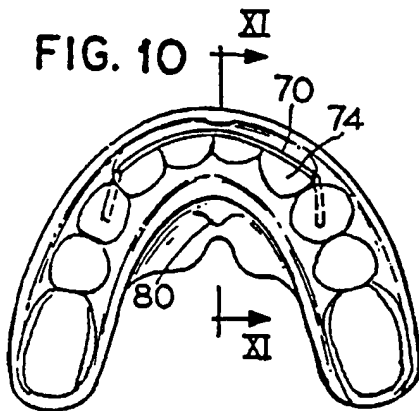


FIG. 10

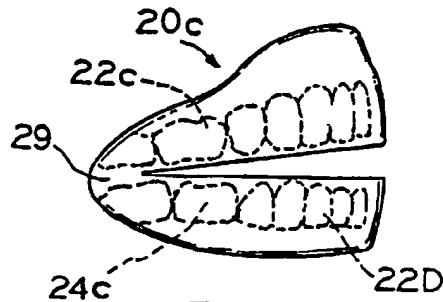


FIG. 15

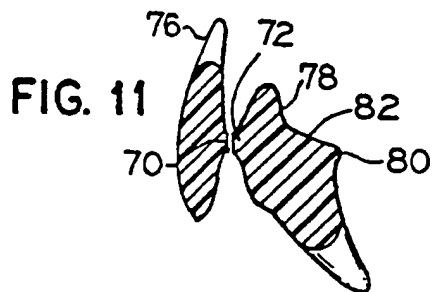


FIG. 11

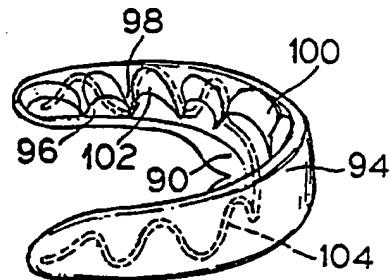


FIG. 14

FIG. 12

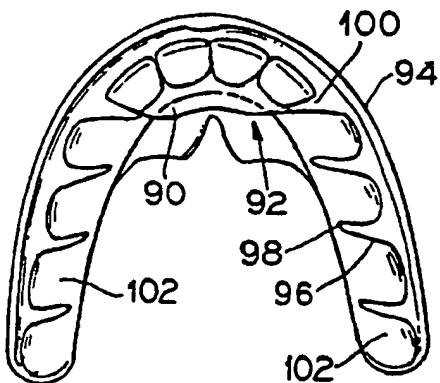
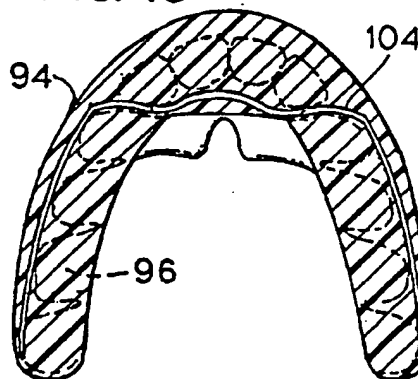


FIG. 13



MULTI-RACIAL PREFORMED ORTHODONTIC TREATMENT APPLIANCE

This is a continuation, of application Ser. No. 08/089, 577, filed Jul. 12, 1993 now abandoned.

BACKGROUND OF THE INVENTION

The present invention relates to an orthodontic appliance, and in particular to an appliance which accommodates multi-racial dentition characteristics.

Various devices and methods have been proposed and used for correcting overcrowding of the teeth and for modifying jaw shapes in order to provide improved teeth placement. Oftentimes metallic bands and wires are used in the permanent dentition stage to provide the desired tooth straightening.

It is also known to use removable appliances in place of metallic bands and wires in order to provide orthodontic tooth positioning treatment and jaw shaping functions. Such removable appliances are generally formed in a U-shape with an upper tooth receiving trough and a lower tooth receiving trough. The appliances are preformed to accommodate various sizes of jaws and dentitions.

It has been recognized that treatment may begin prior to a time at which all deciduous teeth have been replaced by their corresponding permanent teeth through the use of removable appliances such as those disclosed in my U.S. Pat. Nos. 4,139,944 and 4,898,535.

SUMMARY OF THE INVENTION

The present invention provides an improved appliance which can be used by members of different racial groups including Caucasoid, Mongoloid and Negroid. Various enhancements and added features are provided which accommodate usage by the different racial facial characteristics and jaw and mouth constructions. A permanent dentition version appliance will maintain or move erupted permanent incisors, canines, premolars and second molars into the proper arch form accounting for the slightly larger Mongoloid and Negroid arch sizes as compared to the Caucasoid arch sizes. A mixed dentition version will guide erupting permanent incisors, canines, premolars and first molars into the proper arch form. The mixed dentition appliance is also designed to capture high-labially inclined erupting canines and gradually bring them back into a slightly larger arch circumference. A deciduous dentition version will maintain or move deciduous incisors, canines and molars into the proper arch form.

The appliances preferably are preformed in a range of sizes to accommodate various mouth sizes. The arch sizes, flange dimensions and individual tooth socket dimensions and placement are predetermined to accommodate the various mouth sizes.

There are significant correlations between tooth sizes that enables one to calculate rather accurately shapes of teeth relative to each other even before they have erupted into the mouth. Thus, with respect to mixed dentition appliances, this enables a plurality of sizes to be designed such that one is selected from the sizes of the anterior teeth that will accurately fit the permanent posterior teeth and canines as they erupt through tissue and guide them to their correct places.

The margins of the labial flanges in the area of the incisors are positioned at a higher elevation than previously available appliances by up to 0.1 to 10 millimeters. This results in an upper margin of the flange about 10 to 20 mm above the

incisal edge of the central incisor. This enables the appliance to remain in place while sleeping and prevents it from slipping distally and thereby acts in the correction of overjets. With mixed dentition appliances this positions the upper margin high enough to guide canines which erupt labially and are considerably superior to the normal erupting position. This oftentimes occurs in individuals with constricted upper arches and/or slightly larger teeth frequently seen in Negroid and Mongoloid dentitions. This appliance will more easily guide such teeth into position.

This improved appliance will be able to guide, straighten, rotate and adjust the positions of various groups of teeth such as

- (a) the upper four permanent incisors;
- (b) the lower four permanent incisors;
- (c) the upper left posterior segment of permanent canines, bicusps and molars (for permanent dentitions) and deciduous canine and molars (for deciduous and mixed dentitions) and also the upper first left permanent molar (for mixed dentitions);
- (d) the upper right posterior segment of permanent canines, bicusps and molars (for permanent dentitions) and deciduous canine and molars (for deciduous and mixed dentitions) and also the upper first right permanent molar (for mixed dentitions);
- (e) the lower left posterior segment of permanent canines, bicusps and molars (for permanent dentitions) and deciduous canine and molars (for deciduous and mixed dentitions) and also the lower left permanent molar (for mixed dentitions); and
- (f) the lower right posterior segment of permanent canines, bicusps and molars (for permanent dentitions) and deciduous canine and molars (for deciduous and mixed dentitions) and also the lower right permanent molar (for mixed dentitions).

Maintaining the position or moving the position of each permanent incisor, canine, bicuspid, and molar in the mouth by controlling their labial-lingual and buccal-lingual positions is provided by the improved permanent dentition appliance while guiding each permanent canine and bicuspid into the mouth is provided by the improved deciduous and mixed dentition appliance.

The upper and lower arches are controlled as a whole by allowing each to act upon the other by the elongated upper labial margin in the area of the upper four permanent incisors and the excessively-elongated lingual margin of the lower lingual flange relative to the lower four permanent incisors. The upper margin is 0.1 to 10 millimeters higher than in conventional appliances so that it places constant distillizing guidance against the pre-maxilla especially helpful in excessive overjets frequently found in Mongoloid, Negroid and Caucasoid dentitions. As the mouth opens at night during sleep, the appliance will not slip distally past the upper incisors. When the appliance remains in place, the overjet is more ideally corrected.

The lower lingual margin is excessively (0.1 to 10 millimeters) extended gingivally lingual to the lower four permanent incisors to prevent the mandible from slipping distally past the appliance while the patient is sleeping. This also helps in correcting the overjet more effectively in these same racial groups.

The lingual flange in the area of the upper four incisors has alterations on the surface engaging the lingual side of the incisors to accommodate for characteristics in the Mongoloid incisors called shovel-shaped incisors. The very incisal area (the last two millimeters of the centrals and two and

one-half millimeters of the laterals incisally) of the labial flange is formed straight across and the incisal edge is in the range of 0.5-2 millimeters thick labial-lingually so that excessive pressure is placed both vertically and rotationally for all Mongoloid, Caucasoid and Negroid upper incisors. Gingivally from this straight across incisal region, the incisors take on a different shape. Slight depressions or recesses are provided lingually in the flange on both lateral sides of the central and lateral incisors to accommodate the "shovel shaped" anatomy of the typical Mongoloid upper incisal dentition. A slight bulge of 0.1-2 millimeters at each lateral side of the incisors occurs frequently in Mongoloid dentitions. Therefore, recesses of 0.1 to 2 mm which extend laterally slightly are provided so that cleats are more easily placed in this area. The area is designed, due to the thickness, to be able to fit both the Caucasoid and Negroid as well as the Mongoloid dentitions.

The varying width at the bi-canine area in the lower arch for the various sizes of appliances is from 24 to 33 millimeters, while the upper canine-to-canine distance varies from 28 to 38 millimeters. This larger dimension is also carried back distally through the last molar on both the lower and upper troughs.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view partially cut away of a permanent dentition orthodontic appliance embodying the principles of the present invention.

FIG. 1A is a perspective view partially cut away of a mixed dentition orthodontic appliance embodying the principles of the present invention.

FIG. 1B is a perspective view partially cut away of a deciduous dentition orthodontic appliance embodying the principles of the present invention.

FIG. 2 is a plan view of the appliance of FIG. 1.

FIG. 3 is a sectional view taken generally along line III-III of FIG. 2.

FIG. 4 is a side elevational view of the appliance of FIG. 1.

FIG. 5 is a sectional view taken generally along line V-V of FIG. 2.

FIG. 6 is a partial lateral sectional view of an alternate embodiment of the appliance of FIG. 1.

FIG. 7 is a partial sectional view similar to FIG. 6 with a tooth engaged in the appliance.

FIG. 8 is a partial side sectional view of the embodiment of FIG. 6.

FIG. 9 is a partial side sectional view similar to FIG. 8 with a tooth engaged in the appliance.

FIG. 10 is a plan view of an alternate embodiment of the appliance of FIG. 1.

FIG. 11 is a side sectional view taken generally along the line XI-XI of FIG. 10.

FIG. 12 is a plan view of an alternate embodiment of the appliance of FIG. 1.

FIG. 13 is a sectional view through the appliance of FIG. 12.

FIG. 14 is a perspective view of the appliance of FIG. 12.

FIG. 15 is a side elevational view of an alternate embodiment of an orthodontic appliance embodying the principles of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A preformed appliance for straightening and guiding teeth and providing jaw shaping functions for the permanent

dentition is illustrated generally at 20 in FIG. 1. An appliance for the mixed dentition is illustrated generally at 20A in FIG. 1A and for the deciduous dentition generally at 20B in FIG. 1B. Each of the three types are very similar in construction, differing primarily in the distal length of the device (permanent extends to cover at least a part of the second permanent molar, mixed extends to cover the first permanent molar and the deciduous extends to cover the deciduous molars). The sizes of the devices obviously vary to accommodate varying jaw sizes, but in most other respects, the construction is the same, so the description of each of the appliances will be described with reference to the permanent dentition appliance of FIG. 1 unless specific differences pertain.

The appliance or retainer is generally U-shaped in plan view so as to conform to typical human mouth configuration and is generally H-shaped in cross section providing an upper or superior tooth receiving trough 22 and a lower or inferior tooth receiving trough 24. The sides of the troughs 22 and 24 are bounded by a lingual flange 26 which covers the tongue-surface or lingual side of the teeth of the upper and lower arch and a labial and buccal flange 28 which covers the front and cheek-facing surface of the teeth of both arches.

Both the superior and inferior tooth receiving troughs 22, 24 are provided with a plurality of tooth receiving depressions or sockets such as 22a, 22b, 22c, 22d, 22e, 22f and 22g, of different configurations for receiving the different teeth of the mouth from the central incisors through the cuspids, bi-cuspids and terminates approximately half way across the second molar. Alternatively, the appliance can of course be made having only a upper trough 22 or only a lower trough 24.

In the mixed dentition appliance 20A, both the superior and inferior tooth receiving troughs 22A, 24A are provided with a plurality of tooth receiving depressions or sockets such as 22Aa, 22Ab, 22Ac, 22Ad and 22Ae, of different configurations for receiving the different teeth of the mouth from the central incisors through the cuspids first bicuspid, deciduous second molars and terminates at the first permanent molar. Alternatively, the appliance can of course be made having only a upper trough 22A or only a lower trough 24A.

In the deciduous dentition appliance 20B, both the superior and inferior tooth receiving troughs are provided with a plurality of tooth receiving depressions or sockets of different configurations for receiving the different deciduous teeth of the mouth from the central incisors through the cuspids, first deciduous molars and they terminate at the second deciduous molar.

This appliance can be formed to be stiff or flexible, and when flexible can allow for some movement or changes to the shape of the appliance. In the embodiment illustrated in FIGS. 1, 1A and 1B, it does not otherwise have any parts moveable relative to one another. If two troughs are provided, they remain fixed relative to one another.

In the embodiment illustrated in FIG. 15, an appliance 20c is provided which is formed as a split body, one piece member, and in addition to being flexible, and thus allowing some movement or changes to the shape of the appliance, the two troughs 22C, 24C are allowed to move relative to one another by means of a hinge connection 29 provided at a distal end of each trough. The hinge connection is formed such that the device is self-opening, that is, the anterior portions are urged away from one another. An appliance of this type can be used either with permanent dentition, mixed dentition or deciduous dentition.

Such an appliance can be constructed by slitting the plastic or other resilient material appliance along a center parting line (along the direction of the occlusal plane) either at the time of molding or afterwards. If the slit is made at the time of molding, the appliance is immediately spread open and the molded plastic is allowed to cool and thermoset in an opened position so that it takes force to reclose it. The resiliency of the appliance will cause the appliance to be self-opening.

Another method of constructing such an appliance requires the appliance to be cold slit along the same center parting line after the appliance has been molded and has cooled and held open while the plastic at the "hinge" portion is heated up slightly and allowed to thermoset in the opened position. The severity of the cut towards the back or posterior section of the appliance provides for either a weak (further posterior cut) or a strong force to close the appliance on the part of the patient.

The advantages of such an appliance are not only to increase the number of children who can normally keep it in their mouths at night, but also to place a slight depressive force against the anterior (front) teeth in order to correct deep or severe overbites while the users have the appliance in their mouths. This depressive force can also be increased by inserting a flexible and resilient metal plate or spring as a hinge to increase the force necessary to close the mouth when the appliance is in the mouth.

Another advantage of the appliance where the piece is molded with the two halves separated in a flat position with an integral injection molded hinge in between, is that different configurations of dies can be placed in combination with each other as well as moved forward or backward in relation to the bendable portion of the hinge in order to increase or decrease the distance or relation anteriorly or posteriorly (front to back) and thereby create different types of appliances that can correct different severities of malocclusions such as severe Class II, mild Class II, Class I or Class III malocclusions. The hinge portion can also be made thicker or thinner, or wider or narrower, to increase or decrease the force of the hinge.

The appliance illustrated in FIG. 1 is to be used in a permanent dentition stage meaning that all deciduous teeth have been replaced with permanent teeth.

The mixed dentition appliance 20A of FIG. 1A is to be used in a mixed dentition stage meaning that some deciduous teeth have been replaced with permanent teeth, but not all. The sockets provided from the first bicuspid forward (22Aa-22Ad) are the size and in the position of the permanent teeth (FIG. 4) which may not have yet erupted. The large sockets 22Ae distal to the first bicuspid are the size of the deciduous second molar and permanent first molar combined.

The deciduous dentition appliance 20B of FIG. 1B is to be used in a deciduous dentition stage meaning that none of the deciduous teeth have been replaced with permanent teeth. The sockets provided are the size and in the position of the permanent teeth to cause the jaw to expand to the proper desired final size.

The appliance illustrated in FIG. 1 (and also the appliances of FIG. 1A, FIG. 1B and FIG. 15) varies from previously available appliances in that an upper margin 30 (FIGS. 1, 3 and 4) of the labial flange 28 extends gingivally from a tooth receiving surface 32 of the trough 22 to a greater extent than previously provided in these types of appliances. This extension beyond which has not been previously available is by an amount of 0.1 to 10 mm so that

the labial flange will place constant distillizing guidance against the pre-maxilla and will overlie the gingival labial tissue. This extended margin of the flange continues laterally at least to the canines so that when canines erupt labially and are considerably superior to the normal erupting position, the appliance will more easily guide such teeth into position, if being used as the permanent canines erupt. Since previously available appliances had a labial upper flange of up to 10 mm, the present invention contemplates an upper labial flange vertical dimension of 10 to 20 mm.

Similarly, the lower lingual flange has a margin 34 (FIGS. 2 and 3) which is extended gingivally lingual 0.1 to 10 mm beyond that previously provided. This extended margin helps to prevent the mandible from slipping distally past the appliance while the patient is sleeping. Such an arrangement also helps in correcting the overjet more effectively. Thus, the present invention provides for a flange up to 14 or more millimeters from the lower lingual margin and up to 22 mm from the incisal edges of the lower incisors.

As seen in FIG. 2, the upper lingual flange 26 has a plurality of slight recesses 40a, 40b, 40c, 40d, 40e, each extending 0.1 to 2 mm lingually in the incisor area of the appliance. A central or mesial recess 40c is positioned at the mesio-lingual area of the central incisors and extends slightly distally to provide clearance towards the center of each of the central incisors. The next distally spaced recesses 40b, 40d are positioned at the disto-lingual edge of the central incisors and the mesio-lingual edge of the lateral incisors. These recesses 40b, 40d also extend slightly mesially to provide clearance toward the center of the central incisor and distally to provide clearance toward the center of the lateral incisors. Finally, the distal-most recesses 40a, 40e are positioned at the disto-lingual edge respectively of the lateral incisors. Thus, both mesial and distal edges on the lingual side of all four incisors are received in the recesses. These recesses are provided particularly to accommodate characteristics in the Mongoloid incisors called shovel shaped incisors. The wideness of the recesses allow for cleats to be more easily placed in these areas. The recesses terminate short of the incisal area of the flange which represents the last 1.0-3.0 mm incisally of the flange. Cleats can be placed in this area to rotate Caucasoid and Negroid teeth.

The lingual flange at the area of each recess is in the range of 0.5 to 2 mm thick labial-lingually so that excessive pressure is placed both vertically and rotationally on the upper incisors. Since the appliance preferably is fabricated of a resilient plastic material, the resiliency of the material itself will provide the desired pressures on the teeth.

Many other features and arrangements may be incorporated within either the permanent, mixed or deciduous dentition appliances described above in either the single body or split body embodiments. For example, the appliance may be fabricated in a manner to correct for overbite. In order to do this, the thickness of an isthmus 50 extending between the labial-buccal and lingual flanges is varied from that thickness wherein all occlusal surfaces contact substantially concurrently. The thickness is increased in the area of the anterior teeth (incisors) (FIG. 3) relative to the area of the posterior teeth (molars) (FIG. 5) on both sides so that the anterior teeth contact the isthmus 50 first, whereby a depressive force urges the anterior teeth into the gum as the patient attempts to continue to occlude his teeth until the posterior teeth in fact engage. This variation of the isthmus 50 thickness for the correction of the overbite can be accomplished either by reducing the thickness in the area of the posterior teeth (FIG. 5) or increasing the thickness in the area of the anterior teeth (FIG. 3).

However, in view of the fact that the isthmus 50 is already quite thin in the area of the posterior teeth (for example 1.5 mm) it might often be inadvisable to further reduce the thickness at this location so that it would be preferable to effect this variation by increasing the thickness of the isthmus at the anterior teeth. It has been found that an increase in the thickness at the anterior region relative to the posterior region as compared with the normal concurrent occlusion design would optimally be between 4 and 5 mm, thereby causing the anterior teeth to be depressed 1 to 2 mm before contact of the posterior teeth is possible. This arrangement is applicable for either the maxillary or mandibular teeth and can be used in the upper trough 22 and/or the lower trough 24 of an appliance having such an upper and lower trough or in the single trough of a maxillary only or mandibular only trough appliance. The trough could be increased several millimeters to say 10 to 18 mm, however the rear portion would still be only about 2 to 3 mm less than this amount or 7 to 16 mm thick.

The appliance 20 can also be used to correct for open bite and/or retain a previous correction for open bite. Open bite is essentially the opposite of overbite. In this condition the maxillary anterior teeth do not extend downwardly over the front surfaces of the mandibular anterior teeth by a sufficient amount. In accordance with this arrangement, such open bite can be corrected and/or a previous correction for open bite can be retained by simply reversing the variation made for overbite. In this case, the thickness of the isthmus 50 would be increased in the posterior region relative to the anterior region as compared to the thickness of the isthmus when all teeth engage the isthmus substantially concurrently. This would have the effect of exerting depressive forces on the prematurely contacting posterior teeth as the patient attempts to continue occluding the anterior teeth after initial occluding engagement of the posterior teeth. The effect of successful depression of the posterior teeth would of course be that the maxillary anterior teeth could then move farther down over the mandibular anterior teeth before occlusion of the posterior teeth, thereby effecting a correction of open bite. As with the overbite correction, the increase in thickness would optimally cause a premature contacting (in this case of the posterior teeth) of between 1 and 2 mm to correct for the anterior open bite.

As illustrated in the embodiments shown in FIGS. 6-9, the inner surfaces of the appliance may be modified after it has been used to bring the teeth into a desired alignment by reshaping selected tooth depressions 58 exactly to the outer contour of their respective teeth, to thereby firmly hold those selected teeth in a precise position. This reshaping is accomplished by introducing into the selected depressions a soft moldable material 60 which has the property of hardening at body temperature after a short period of time and adhering permanently to the appliance itself. With this material, the appliance is placed into the patient's mouth, centered properly therein, and the patient is asked to close his teeth and hold them together for a few minutes until the material hardens. The appliance is then removed and when the material has completely hardened it is trimmed at the margins of the tooth depressions. As a result, there is provided a tooth appliance originally preformed or custom-made for the purpose of moving teeth to a desired position, and further including a liner material within selected tooth depressions, which liner is shaped essentially precisely to the outer contour of the tooth received therein, thereby firmly holding this tooth in the position which it has reached up to this point. The use of liner material is applicable of course to either a maxillary appliance, a mandibular appliance or a combined maxillary-mandibular appliance.

The material of the liner may be one that becomes relatively hard at body temperature or one which is relatively resilient or rubber-like at body temperature. If a hard material is used, it has the advantage that the appliance will snap in place quite firmly as the occlusal surfaces of the teeth move into their respective depressions, pushing aside the hard material at the gingival edges of the depressions which are provided for pressing against the undercut portions of the teeth adjacent the gums when the teeth are firmly in place in their respective depressions. Alternatively, if the liner material is relatively resilient, it might not have the same firm positive action as with the harder material but apparently with a resilient material it is possible to more closely and precisely fit the outer contour of the teeth. Indeed, the advantages of both the hard and the soft materials can be achieved in a single embodiment utilizing a material which is hard at body and room temperature but which becomes rubbery a few degrees thereabove. This material can have the advantages of both in that the patient can warm the finished realigned appliance in hot water, place it in his mouth, after which it will slowly harden and function like the hard liner material by firmly holding the teeth in place.

Many materials are known which could be utilized to form the liner material. Preferably, materials would be used which would polymerize, chemically bond with or otherwise strongly adhere to the material of the appliance itself or with an additional material applied thereto for that purpose. For example, the preformed or custom made appliance could be made of a polymer or copolymer of the same material or of a material which would provide an adhering surface for the insert material. This might include for example a material with a small percentage by weight of acrylic resin which would thus provide a perfect adhering surface for a self-cure acrylic polymer which would remain permanently attached thereto. A methyl-methacrylate monomer may be painted on the surface of the appliance where the liner material is to be added, after which this monomer and the self-cure acrylic polymer are mixed into a runny consistency and placed onto the painted surface. With the appliance in this state, the appliance would be placed into the patient's mouth, centered properly, and the patient would be asked to close his teeth and hold them together for a couple of minutes until the material hardens. After hardening, the material would be trimmed and polished.

FIGS. 6 and 8 illustrate the upper lateral incisor tooth depression with the liner material therein. In FIG. 6 the liner material is shown as it might extend slightly up into the space between this tooth and its adjacent tooth while FIG. 8 illustrates how the material might run up to the upper edge of the depression so as to mate with the undercut portions of the labial and lingual sides of the tooth. FIGS. 7 and 9 illustrate the modified depressions of FIGS. 6 and 8 with a lateral incisor tooth located therein.

FIGS. 10-11 illustrate another embodiment of the present invention in which a vertical slit 70 is provided in the isthmus 72 in the region of the sockets 74 for at least the incisors as shown in solid lines and, in some cases to include the socket region for the canines (usually for adult usage) as illustrated by dashed lines. It should be understood that the slit 70 may be a through-slit which extends completely through the appliance, or it may be an opposed pair of channels or recesses or a partial slit so long as it is sized and shaped to allow the teeth to erupt vertically without resistance. In this manner the isthmus 72 interconnects the flanges 76, 78 only in the posterior portion of the appliance and does not interconnect the flanges in the anterior portion. The vertical slit 70 ensures that no pressure will be applied

to the incisors (and possibly canines) in a vertical direction when the user of the appliance bites thereon. The isthmus 72 which is solid in the region of the posterior teeth will prevent further eruption of those teeth while the slit will encourage further eruption of the anterior teeth to assist in the correction of the open bite condition.

This embodiment also includes a molded inset 80 which preferably is molded integrally with the appliance, the inset being molded to the lingual region of the appliance as a reminder guide for the tip of the tongue. The inset 80 includes one or more pointed protrusions which may be positioned along the lower midline portion of the appliance or laterally spaced from the midline, on the lingual side, to discourage the tongue from assuming an anterior and depressed position. The contour of the appliance along the midline, as best seen in FIG. 11, also includes a recessed area 82 superior to the protrusions which encourages the tongue to assume a higher vertical position especially when used in combination with the pointed protrusions. The addition of this molded inset 80 serves to encourage proper tongue positioning, thereby overcoming the anterior tongue thrust problem which tends to worsen the open bite condition.

A further embodiment is illustrated in FIGS. 12-14. In this embodiment the lingual flange 90 is provided at an anterior bight portion 92 of the U-shaped appliance to overlie a lingual surface of at least one of an upper or lower set of central and lateral incisors. The lingual flange terminates prior to the canine so that the patient's tongue will be free to engage the lingual surface of the posterior teeth (canines and molars). The labial/buccal flange 94 may be configured so as to hold the cheeks and lips away from the buccal and labial surfaces of the patient's teeth.

The appliance preferably is a preformed or custom-made device fabricated of a molded resilient material such as plastic that conforms to the anterior teeth (central and lateral incisors) and, the buccal flange 94 is spaced laterally away from the posterior teeth. Thus, the force of the tongue against the posterior teeth causes these teeth to move buccally to gain extra room for the patient's crowded or potentially crowded teeth.

A lingual surface 96 of the buccal shield is notched in that it has lingually extending projections 98 extending therefrom. The projections 98 are positioned to project into the interproximal spaces between each of the posterior teeth and a wedge-shaped projection 100 is provided between the canines and the lateral incisors. The projections are angled anteriorly and lingually from their points of attachment at the buccal flange to thereby define a buccally and posteriorly directed slot or pocket 102 for receiving each of the posterior teeth. A slanting of the projections encourages each buccal tooth to assume an expanded position while gaining space anteriorly between the canine and the lateral incisors where the space can be used for the elimination of crowding in the anterior segment, especially in the lateral-canine area. Preferably the expansion of the buccal shield allows for approximately 1 to 20 mm of expansion between the canines in the upper and lower arches as well as approximately 1-20 mm of lateral expansion between each of the molars. Expansion may be provided for the anterior segment if desired or needed, but in some instances no anterior segment expansion would be required.

The wedged shaped projection 100 between the lateral incisors and the canines causes the canines to drift distally along a distal surface of the wedge to assume a more expanded but slightly distal position. As each tooth distal of the canine is expanded, it in turn migrates slightly distally or

at least does not move mesially as it expands. In this way, the excess space created by the posterior expansion ends up in the lateral-canine area.

It may also be preferable to include a wire member 104 molded into the interior of the appliance to assist in maintaining the desired buccal expansion dimension or other configuration of the appliance. The wire may have a serpentine shape as best seen in FIG. 14 to permit adjustments of the appliance horizontally as well as vertically or a combination of horizontal and vertical in a compound bend.

The appliance embodying the present invention may be provided with a means for determining the amount of usage of the appliance by the patient. A specific problem facing the orthodontist is that of obtaining full cooperation of the patient in utilizing the device. On occasion, a patient having been instructed to wear an appliance for certain periods of time each day will return to the orthodontist's office at which time the orthodontist will observe that the progress in terms of movement of teeth has not been satisfactory. It is critically important that the orthodontist be aware of the reason for such insufficient progress. Specifically, it might be because of an individual resistance to tooth movement, an improperly fitting appliance or simply due to the fact that the patient does not wear the appliance as instructed. Thus, the appliance may be formed of a material such that under normal conditions it is essentially transparent, but wherein the appliance has the characteristic of changing opacity in proportion to the time the appliance is in the mouth. As a result thereof, if a patient returns to the orthodontist office with insufficient progress, the orthodontist can then simply visually inspect the appliance to determine whether or not the patient has in fact been using the appliance.

Although there are perhaps many materials with which the appliance may be made, in a preferred embodiment, the material of the appliance is a soft pliable plastic that softens and melts at rather high temperatures. Early plastics were known to have the disadvantage that they absorbed moisture and became cloudy. This is known as water-blush plastic. Over the years, however, many varieties of plastics were developed including means for eliminating this water-blush characteristic such that they remain transparent even when subjected to high moisture conditions.

In the preferred embodiment the appliance is made by mixing together a proportion of water-blush and a portion of non-water blush plastic. The proportion of water-blush to non-water blush plastics can be varied quite widely, however the proportion should preferably be selected so as to retain at least some transparency as a diagnostic aid even during full cooperation.

In addition, the proportion should of course be selected with direct reference to the period of time that it is contemplated the patient will be instructed to wear the appliance. That is, the proportions should be chosen such that after the correct time of wear, the appliance will have a high level of opacity consistent with the need for a certain degree of transparency.

It has been determined that a range from about 25% water-blush to about 75% water-blush plastic provides both meaningful indication of wear as well as the necessary transparency.

The appliance may also be made of a molding consisting of a moldable base material, the moldable base material being sufficiently absorptive to permit a recharging of the appliance with fluoride by soaking the appliance in a fluoridating material. The base material may be made of an absorbent blush plastic admixed prior to melting and shap-

ing with a fluoridating material and a concentration varying from 0.01 milligrams to 200 milligrams per milliliter or 0.01% to 70% by weight. A recharge of fluoride may be given to the appliance periodically or there can be an alternative method of delivery by soaking the appliance in the fluoride compound. Certain areas of the appliance can also be soaked such as only around the tooth areas by placing the chemicals into the sockets and allowing them to be absorbed into the soluble type plastic. In this way, the fluoride chemicals are mostly present at the tooth surface and not on the cheek surface so any potential irritation on the cheeks is avoided.

As is apparent from the foregoing specification, the invention is susceptible of being embodied with various alterations and modifications which may differ particularly from those that have been described in the preceding specification and description. It should be understood that I wish to embody within the scope of the patent warranted hereon all such modifications as reasonably and properly come within the scope of my contribution to the art.

I claim as my invention:

1. An orthodontic appliance which is preformed to be generally U-shaped in plan view and includes a preformed tooth receiving trough formed between lingual and labial/buccal side flanges in at least an upper side thereof, which trough includes prefabricated tooth receiving depressions of predetermined dimensions for receiving and positioning teeth from central and lateral incisors to and including at least a molar, said appliance, trough and depressions being preformed of said predetermined dimensions without reference to a particular patient's dentition, said labial/buccal flange, in an area adapted to engage said incisors, extending gingivally from a tooth receiving surface of said trough by more than 10 mm so as to constantly engage a patient's gingival labial tissue and place constant distillizing guidance against a patient's pre-maxilia, said lingual flange having laterally spaced apart, vertically oriented lingually extending recesses of 0.1 to 1 mm in depth which extend slightly laterally at a mesial area and a distal edge of the central incisors and at a distal edge and a mesial edge of the lateral incisors so as to be positioned adjacent to the lateral edges of a lingual side of all four incisors, said recesses being defined by adjacent portions of said lingual flange which are not recessed and which are adapted to engage the lateral edges of the lingual side of all four incisors.

2. An orthodontic appliance according to claim 1, wherein said appliance includes upper and lower troughs and said lingual flange defining said lower trough extends gingivally and lingually more than 8 mm in the area of said lower incisors.

3. An orthodontic appliance according to claim 1, wherein said upper lingual trough has laterally spaced apart, vertically oriented lingually extending recesses of 0.1 to 1 mm which extend slightly laterally at a mesial area and distal edge of the central incisors and at a distal edge and mesial edge of the lateral incisors so as to overlies the lateral edges of all four incisors.

4. An orthodontic appliance according to claim 3, wherein said upper labial flange at said recesses is 0.5 to 2 mm thick labial-lingually.

5. An orthodontic appliance according to claim 1, wherein said appliance comprises a molding consisting of a moldable base material, said moldable base material being sufficiently absorbative to permit a recharging of the appliance by soaking the appliance in fluoridating material, and wherein said base material is an absorbent blush plastic admixed prior to melting and shaping with a fluoridating material in

a concentration varying from 0.01 mg. to 200 mg. per milliliter or 0.01% to 70% by weight.

6. An orthodontic appliance according to claim 1, wherein said appliance is formed of a material which is normally essentially transparent under normal room conditions and which increases in opacity by absorption of moisture when placed in a patient's mouth for a predetermined period of time.

7. An orthodontic appliance according to claim 1, wherein said flanges are connected by an isthmus, a thickness of said isthmus being greater at an anterior portion of said appliance than at a posterior portion such that as the side thereof opposite the trough rests against the occlusal surfaces of the row other than said one row, the anterior teeth of said one row engage the isthmus before the posterior teeth of said one row to exert a force against the anterior teeth depressing them into the gum to correct for overbite or to retain a previous overbite correction as the posterior teeth complete their movement towards engagement with the isthmus.

8. An orthodontic appliance according to claim 1, wherein said flanges are connected by an isthmus, a thickness of said isthmus being greater at a posterior portion of said appliance than at an anterior portion such that as the side thereof opposite the trough rests against the occlusal surfaces of the row other than said one row, the posterior teeth of said one row engage the isthmus before the anterior teeth of said one row to exert a force against the posterior teeth depressing them into the gum to correct for open bite or to retain a previous open bite correction as the anterior teeth complete their movement towards engagement with the isthmus.

9. An orthodontic appliance according to claim 1, wherein said appliance is formed of an elastomeric material, and said trough has one or more selected depressions therein shaped substantially precisely to the outer contour of a respective tooth sufficiently to hold said respective tooth in a fixed position relative to said appliance, said appliance comprising a substrate in the shape of a conventional appliance shaped to correct and retain teeth within the patient's mouth, and including a liner forming a discontinuous phase with respect to the substrate within the selected one or more depressions to form the portion of outer contour of said selected teeth.

10. An orthodontic appliance according to claim 1, wherein said flanges are connected by an isthmus, said isthmus having a vertical slit in an anterior portion of said appliance which is engaged by at least some of the central incisor, lateral incisor and canine anterior teeth.

11. An orthodontic appliance according to claim 1, wherein said flanges are connected by an isthmus and means for guiding the tongue including at least one pointed protrusion formed on the lingual side of the lower midline portion of the appliance and a recessed area superior to the protrusion for receiving a tip of the tongue.

12. An orthodontic appliance according to claim 1, wherein said buccal flange includes a plurality of projections defining tooth receiving slots therebetween extending longitudinally from said buccal flange, said projections being spaced to project between each of the posterior teeth of the patient.

13. An orthodontic appliance according to claim 1, wherein said appliance includes at least one wire molded therein for retaining said appliance in a desired shape.

14. An orthodontic appliance according to claim 1, for use with a permanent dentition, wherein said appliance extends posteriorly to a position to engage a second permanent molar.

15. An orthodontic appliance according to claim 1, for use with a mixed dentition, wherein said appliance extends posteriorly to a position to engage a first permanent molar.

16. An orthodontic appliance according to claim 1, for use with a deciduous dentition, wherein said appliance extends posteriorly to a position to engage a deciduous molar.

17. An orthodontic appliance according to claim 1, wherein said appliance is formed as a single body member with an upper trough and a lower trough permanently fixed relative to one another.

18. An orthodontic appliance according to claim 1, wherein said appliance is formed as a split body member with an upper trough and a lower trough hinged together at distal ends thereof.

19. An orthodontic appliance which is preformed to be generally U-shaped in plan view and includes a preformed tooth receiving trough formed between lingual and labial/buccal side flanges in at least an upper side thereof, which trough includes prefabricated tooth receiving depressions of predetermined dimensions for receiving and positioning teeth from central and lateral incisors to and including at least a molar, said appliance, trough and depressions being preformed of said predetermined dimensions without reference to a particular patient's dentition, said lingual flange having laterally spaced apart, vertically oriented lingually extending recesses of 0.1 to 1 mm in depth which extend slightly laterally at a mesial area and a distal edge of the central incisors and at a distal edge and a mesial edge of the lateral incisors so as to be positioned adjacent to the lateral edges of a lingual side of all four incisors, said recesses being defined by adjacent portions of said lingual flange which are not recessed and which are adapted to engage the lateral edges of the lingual side of all four incisors.

20. An orthodontic appliance according to claim 19, wherein said labial flange at said recesses is 0.5 to 2 mm thick labial-lingually.

21. An orthodontic appliance according to claim 20, wherein said appliance is fabricated of a resilient plastic material so that excessive pressure is placed both vertically and rotationally on the incisors engaged by said lingual flange.

22. An orthodontic appliance of the type which is preformed to be generally U-shaped in plan view and includes a preformed tooth receiving trough formed between lingual and labial/buccal side flanges in at least a lower side thereof, which trough includes prefabricated tooth receiving depressions of predetermined dimensions for receiving and positioning teeth from central and lateral incisors to and including at least a molar, said appliance, trough and depressions being preformed of said predetermined dimensions without reference to a particular patient's dentition, said lingual flange, in an area of said incisors, extending gingivally and lingually more than 8 mm so as to overlies a patient's gingival lingual tissue and place constant correcting guidance against a patient's overjet and preclude the appliance from slipping distally past the patient's mandible, said lingual flange having laterally spaced apart, vertically oriented lingually extending recesses of 0.1 to 1 mm in depth which extend slightly laterally at a mesial area and a distal edge of the central incisors and at a distal edge and a mesial edge of the lateral incisors so as to be positioned adjacent to the lateral edges of a lingual side of all four incisors, said recesses being defined by adjacent portions of said lingual flange which are not recessed and which are adapted to engage the lateral edges of the lingual side of all four incisors.

23. An orthodontic appliance according to claim 22, wherein said appliance comprises a molding consisting of a moldable base material, said moldable base material being sufficiently absorbative to permit a recharging of the appli-

ance by soaking the appliance in fluoridating material, and wherein said base material is an absorbent blush plastic admixed prior to melting and shaping with a fluoridating material in a concentration varying from 0.01 mg. to 200 mg. per milliliter or 0.01% to 70% by weight.

24. An orthodontic appliance according to claim 22, wherein said appliance is formed of a material which is normally essentially transparent under normal room conditions and which increases in opacity by absorption of moisture when placed in a patient's mouth for a predetermined period of time.

25. An orthodontic appliance according to claim 22, wherein said flanges are connected by an isthmus, a thickness of said isthmus being such that as the side thereof opposite the trough rests against the occlusal surfaces of the row other than said one row, the anterior teeth of said one row engage the isthmus before the posterior teeth of said one row to exert a force against the anterior teeth depressing them into the gum to correct for overbite or to retain a previous overbite correction as the posterior teeth complete their movement towards engagement with the isthmus.

26. An orthodontic appliance according to claim 22, wherein said flanges are connected by an isthmus, a thickness of said isthmus being such that as the side thereof opposite the trough rests against the occlusal surfaces of the row other than said one row, the posterior teeth of said one row engage the isthmus before the anterior teeth of said one row to exert a force against the posterior teeth depressing them into the gum to correct for open bite or to retain a previous open bite correction as the anterior teeth complete their movement towards engagement with the isthmus.

27. An orthodontic appliance according to claim 22, wherein said appliance is formed of an elastomeric material, and said trough has one or more selected depressions therein shaped substantially precisely to the outer contour of its respective tooth sufficiently to hold its respective tooth in a fixed position relative to said appliance, said appliance comprising a substrate in the shape of a conventional appliance shaped to correct and retain teeth within the patient's mouth, and including a liner forming a discontinuous phase with respect to the substrate within the selected one or more depressions to form the portion of outer contour of said selected teeth.

28. An orthodontic appliance according to claim 22, wherein said flanges are connected by an isthmus, said isthmus having a vertical slit in an anterior portion of said appliance which is engaged by at least some of the central incisor, lateral incisor and canine anterior teeth.

29. An orthodontic appliance according to claim 22, wherein said flanges are connected by an isthmus and means for guiding the tongue including at least one pointed protrusion formed on the lingual side of the lower midline portion of the appliance and a recessed area superior to the protrusion for receiving a tip of the tongue.

30. An orthodontic appliance according to claim 22, wherein said buccal flange includes a plurality of projections defining tooth receiving slots therebetween extending longitudinally from said buccal flange, said projections being spaced to project between each of the posterior teeth of the patient.

31. An orthodontic appliance according to claim 22, wherein said appliance includes at least one wire molded therein for retaining said appliance in a desired shape.

32. A series of differently sized orthodontic appliances which are each preformed to be generally U-shaped in plan view and include a preformed tooth receiving trough formed between lingual and labial/buccal side flanges in at least an

upper side thereof, which trough includes prefabricated tooth receiving depressions of predetermined dimensions for receiving and positioning teeth from central and lateral incisors to an including at least a molar, said appliances, trough and depressions being preformed of said predetermined dimensions without reference to a particular patient's dentition, said labial/buccal flange in an area adapted to engage said incisors, extending gingivally from a tooth receiving surface of said trough by more than 10 mm so as to constantly engage a patient's gingival labial tissue and provide constant distillizing guidance against a patient's pre-maxilla, said lingual flange having laterally spaced apart, vertically oriented lingually extending recesses of 0.1 to 1 mm in depth which extend slightly laterally at a mesial area and a distal edge of the central incisors and at a distal edge and a mesial edge of the lateral incisors so as to be positioned adjacent to the lateral edges of a lingual side of all four incisors, said recesses being defined by adjacent portions of said lingual flange which are not recessed and which are adapted to engage the lateral edges of the lingual side of all four incisors.

33. A series according to claim 32, wherein said appliances are preformed in a range of different sizes to accommodate different sized mouths and stages of dentition.

34. The series according to claim 32 further comprising a preformed tooth receiving trough formed between lingual and labial/buccal side flanges in a lower side thereof, said lingual flange, in an area adapted to engage said incisors, extending gingivally and lingually more than 8 mm so as to constantly overlie a patient's gingival lingual tissue and to place constant correcting guidance against a patient's overjet

and to preclude the appliance from slipping distally past the patient's mandible.

35. A series of differently sized orthodontic appliances which are each preformed to be generally U-shaped in plan view and include a preformed tooth receiving trough formed between lingual and labial/buccal side flanges in at least a lower side thereof, which trough includes prefabricated tooth receiving depressions of predetermined dimensions for receiving and positioning teeth from central and lateral incisors to and including at least a molar, said appliance, trough and depressions being preformed of said predetermined dimensions without reference to a particular patient's dentition, said lingual flange, in an area adapted to engage said incisors, extending gingivally and lingually more than 8 mm so as to constantly overlie a patient's gingival lingual tissue and place constant correcting guidance against a patient's overjet and preclude the appliance from slipping distally past the patient's mandible, said lingual flange having laterally spaced apart, vertically oriented lingually extending recesses of 0.1 to 1 mm in depth which extend slightly laterally at a mesial area and a distal edge of the central incisors and at a distal edge and a mesial edge of the lateral incisors so as to be positioned adjacent to the lateral edges of a lingual side of all four incisors, said recesses being defined by adjacent portions of said lingual flange which are not recessed and which are adapted to engage the lateral edges of the lingual side of all four incisors.

36. A series according to claim 35, wherein said appliances are preformed in a range of different sizes to accommodate different sized mouths and stages of dentition.

* * * * *

EXHIBIT C

[54] ORTHODONTIC POSITIONER AND METHOD OF MANUFACTURING SAME

[76] Inventor: Lawrence F. Andrews, 2025 Chatsworth Blvd., San Diego, Calif. 92107

[21] Appl. No.: 657,308

[22] Filed: Oct. 3, 1984

[51] Int. Cl.⁴ A61C 3/00

[52] U.S. Cl. 433/6; 433/187

[58] Field of Search 433/6, 184, 187; 128/136

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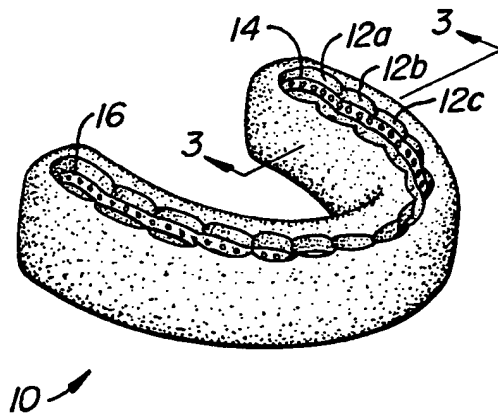
Primary Examiner—John J. Wilson

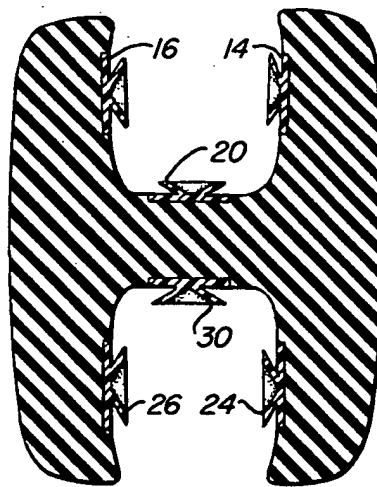
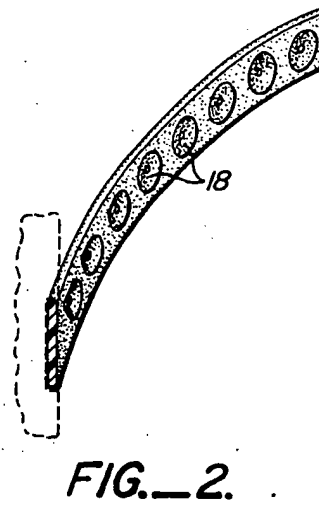
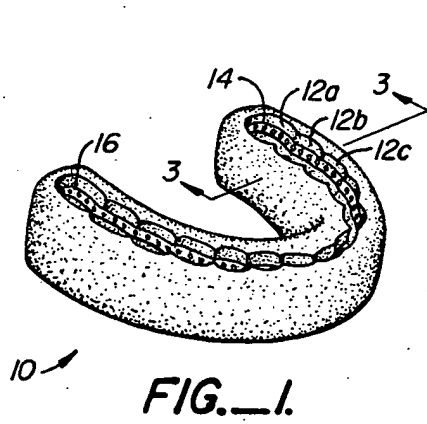
Attorney, Agent, or Firm—Townsend and Townsend

[57] ABSTRACT

An improved orthodontic positioner provides a series of tiny suction devices on the tooth confronting walls of the positioner. These suction devices provide increased adherence of the positioner to the top, inner and outer tooth surfaces of the patient's teeth, and act to mechanically hold the teeth firmly together in their desired place within the positioner.

5 Claims, 3 Drawing Figures





ORTHODONTIC POSITIONER AND METHOD OF MANUFACTURING SAME

BACKGROUND OF THE INVENTION

1. Field of the Invention.

This invention relates generally to dental equipment and practices, and specifically to an improved orthodontic positioner for improving the position of a patient's teeth, and a method for its manufacture.

2. Description of the Prior Art

In standard orthodontic practice, sometimes several steps are utilized to achieve the desired degree of straightening and positioning of the teeth. Typically, orthodontic braces utilizing first a system of bands, brackets, and wires, that are installed on the teeth, are left in place for a period of time to mechanically orient the imperfect occlusion. However, when bands are used they occupy significant space in and around the teeth, making it impossible to fully complete treatment until they are removed. Precise vertical positioning of the teeth is also difficult to achieve fully with braces. Final correction requires some slight further tooth movement to complete space closure and vertical positioning. This is usually accomplished through the use of an orthodontic positioner, which is an elastic structure much in the form of a boxer's mouthpiece.

The positioner is made by first constructing plaster reproductions of the patient's actual teeth at the end of the braces portion of treatment. These reproductions are placed into the ideal alignment desired for the patient's actual teeth. Pliable rubber or silicone plastic is then molded around these ideally positioned teeth, then cured to a permanent but still elastic form. The resulting set of impressions in the cured positioner material thus correspond to the desired ultimate positioning of the patient's teeth. The completed positioner is then inserted into the mouth by the patient and, by clenching the teeth, are contacted by the molded impressions in the positioner and are thus urged into their ideal positions.

Such conventional orthodontic positioners are well known. However, most of these devices are hindered in their operation by an inherent biological fact of life—that is, for most of the time, a patient's jaws are relaxed. Thus, when the orthodontic positioner is in place in the user's mouth, the patient must actively keep his teeth clenching for the positioner to work. Jaw physiology, human nature and fatigue being what they are, the user is prone to let his jaws relax, allowing the teeth to leave their ideal locations within the positioner, thus reducing the efficiency of the entire system. Therefore, the rate of tooth movement is slower than optimum which increases the length of time that the positioner must be worn to achieve ideal tooth alignment.

SUMMARY OF THE INVENTION

The present invention provides an improved orthodontic positioner which assists in keeping the patient's teeth together through the use of a series of tiny suction devices on the tooth confronting walls of the positioner. These suction devices provide increased adherence of the positioner to the top, inner, outer, and around the rear surface of the last tooth of the patient's dentition, thus mechanically holding the teeth firmly together in their desired place within the positioner. This improved retention of the patient's teeth within the positioner

accelerates the desired tooth movement and correction because the force is more continuous.

Furthermore, the incorporation of these suction devices on the tooth confronting walls of the positioner serves to add a second level of flexibility to the positioner, in addition to the level of flexibility achieved by the natural flexibility of the substance used to make the positioner itself. It is believed that this additional flexibility enhances the gentle urging of the teeth to their desired positions, thus accelerating the rate of movement and reducing the amount of time the positioner must be worn.

In the preferred embodiment, the suction devices are formed of tiny elastic suction cups (e.g., rubber, silicone, etc.), each no wider than the tooth surface it must confront, and ideally much smaller. In fact, it is desirable to have a plurality of suction cups placed in the positioner to confront the top, inner and outer surfaces of each tooth in question. These suction cups present small, hemispherically-shaped flexible surfaces to the teeth they confront, and, when pressed into place by biting, provide a gentle but significant suction to grab and direct the teeth to their desired position with the body of the positioner providing the outer constraints of control.

The improved orthodontic positioner of this invention is preferably made in the following manner: first, as in the construction of a conventional orthodontic positioner, plaster reproductions of the patient's actual teeth are made. The teeth of these plaster reproductions are then arranged so that they represent the ideal alignment desired for the patient's actual teeth. A plurality of suction devices, preferably in the form of "strips" of tiny suction cups, are then placed on the top, inner and outer surfaces of these plaster teeth, so that each tooth's surface is contacted by at least one, and preferably a plurality, of suction devices. A flexible, formable material, such as rubber, silicone, plastic or the like, is then formed around the plaster reproductions with the suction devices intact. The semi-liquid material is cured and allowed to solidify. The plaster cast is then removed from the newly cured positioner. In this way, the suction devices are integrally incorporated into the walls of the orthodontic positioner, yielding a perfect, custom tailored pattern to which the patient's actual teeth can conform.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of the improved orthodontic positioner of this invention;

FIG. 2 is a perspective view of a strip of suction devices; and

FIG. 3 is a cross-sectional view taken along line 3—3 of FIG. 1.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 is a perspective view of an orthodontic positioner 10, with molded depressions 12a, b, etc., corresponding to the individual teeth in the arrangement from which the positioner was cast. The first strip of suction devices 14 is shown on the wall of positioner 10 which will confront the outer surface of that row of teeth. A second strip of suction devices 16 is shown on the wall of positioner 10 which will confront the inner surface of that row of teeth. Further strips of such suction devices are located on the wall of positioner 10

which will confront the top (or chewing) surface of the teeth but these cannot be seen in the view of FIG. 1.

FIG. 2 is a view of a strip of suction devices, showing the individual suction cups 18 mounted in strip form. Of course, there can be any number of suction cups 18 5 located on the strip.

FIG. 3 is a cross-sectional view taken along line 3—3 of FIG. 1. In this view, outer strip 14 and inner strip 16 can be seen on their respective walls while top or chewing surface strip 20 can now be seen as it would confront that surface of the teeth. There can be, of course, a corresponding set of depressions and strips of suction devices on the positioner of the lower set of the patient's teeth. This is indicated in FIG. 3 by lower outer strip 24, lower inner strip 26 and lower chewing strip 30. 15

What is claimed as invention is:

1. An orthodontic positioner for urging at least one of a dental patient's teeth from an actual position to a desired position, the orthodontic positioner comprising:
 - a flexible mouthpiece formed to have therein impres- 20 sions of the desired positions of the teeth; and
 - a tooth-adhering portion comprising a suction device interior of at least one of the impressions for grasping a selected tooth and urging the selected tooth from the actual position to the desired position 25 with suction forces.
2. An orthodontic positioner comprising:
 - a flexible mouthpiece into which impressions of the desired alignments of a dental patient's teeth have been made, at least one of said desired alignment 30 being different from an actual alignment of at least one selected tooth, to be worn by the patient to urge the at least one selected tooth into such de-

sired alignment by applying gentle pressure to the at least one selected tooth along tooth-confronting surfaces of said positioner; and

- a tooth adhering portion comprising a suction device interior of at least one of the impressions to increase the adherence of said positioner to at least one of said teeth, and more securely maintain said teeth within said positioner, the suction device being positioned to confront a surface of the at least one selected tooth and thereby urge the at least one selected tooth toward said desired alignment.

3. The orthodontic positioner of claim 1 wherein said suction device comprises a suction cup member presenting a flexible hemispherically-shaped surface to said teeth. 15

4. The orthodontic positioner of claim 1 wherein said positioner includes surfaces for confronting the top, inner and outer surfaces of said teeth and said tooth adhering portion comprises strips of suction cups carried on each of said tooth confronting surfaces.

5. A method manufacturing an orthodontic positioner comprising the steps of:

- providing solid reproductions of a patient's teeth;
- arranging said reproductions in a mold so they represent the ideal alignment of said patient's teeth;
- placing a plurality of suction devices on the top, inner and outer surfaces of said reproductions;
- pouring a flexible material around these plaster reproductions with said suction devices intact;
- allowing said flexible material to solidify; and
- removing the resulting cast from the reproduction mold.

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EXHIBIT D



US005328362A

United States Patent [19]

Watson et al.

[11] Patent Number: 5,328,362

[45] Date of Patent: Jul. 12, 1994

[54] SOFT RESILIENT INTEROCCLUSAL DENTAL APPLIANCE, METHOD OF FORMING SAME AND COMPOSITION FOR SAME

[76] Inventors: Sherman L. Watson, 12716 NE. 7th Pl., Vancouver, Wash. 98684; Jimmie J. Jones, 4416 SE. 34th St., Portland, Oreg. 97202; Richard W. Moore, 2103 NW. 272nd Ave., Camas, Wash. 98607

[21] Appl. No.: 849,467

[22] Filed: Mar. 11, 1992

[51] Int. Cl.⁵ A61C 3/00

[52] U.S. Cl. 433/6; 128/861; 523/115; 523/120

[58] Field of Search 523/115, 120; 433/6; 128/861, 862

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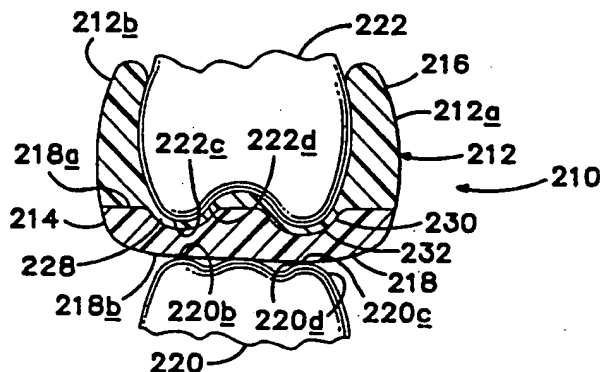
Attorney, Agent, or Firm—Kolisch, Hartwell, Dickinson, McCormack & Heuser

[57]

ABSTRACT

A unitary plural-material, interocclusal dental appliance is disclosed for use in connection with orthodontic/orthopedic treatment of the teeth and jaws of a patient's mouth. The appliance includes a first region made from a first material that provides a relatively hard expanse with first and second surfaces, and with the second surface being contactable by one such set of teeth. The second surface may be constructed with a substantially planar shape, or with a shape conforming generally to the cusps of such one set of teeth. A second region is joined to the first region, and is made from a second material that provides a relatively soft, persistently resilient enclosure for the other such set of teeth. The second region includes plural zones, each of which is structured to allow an adjacent enclosed tooth to move toward the first surface of the first region, with such movement resulting in penetration of corresponding teeth into the relatively hard first material for a relatively precise distance. Such penetration defines lateral borders in the first material around such teeth so that the appliance accommodates relatively fixed vertical and lateral positioning of the mandible by enclosing such teeth upon desired biting action by the patient. A method for forming such appliance is also disclosed. Additionally, a curable composition for making a soft, persistently resilient dental appliance is disclosed and it includes a polymer component including butyl methacrylate polymer, and a monomer component including butyl methacrylate monomer.

22 Claims, 3 Drawing Sheets



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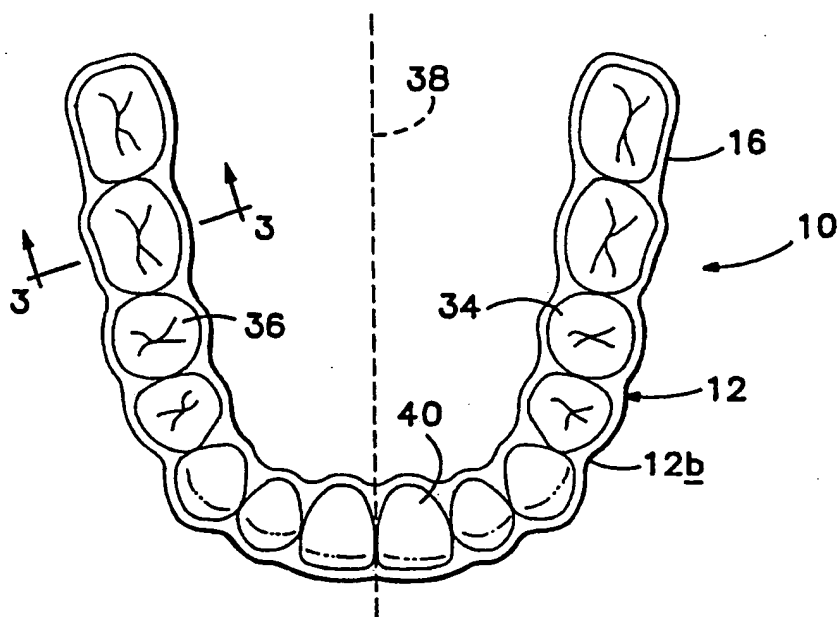


Fig. 1

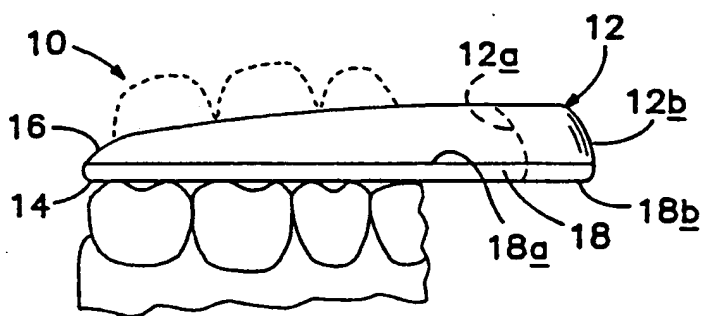


Fig. 2A

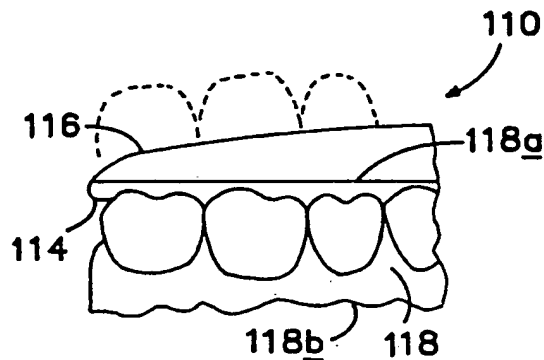


Fig. 2B

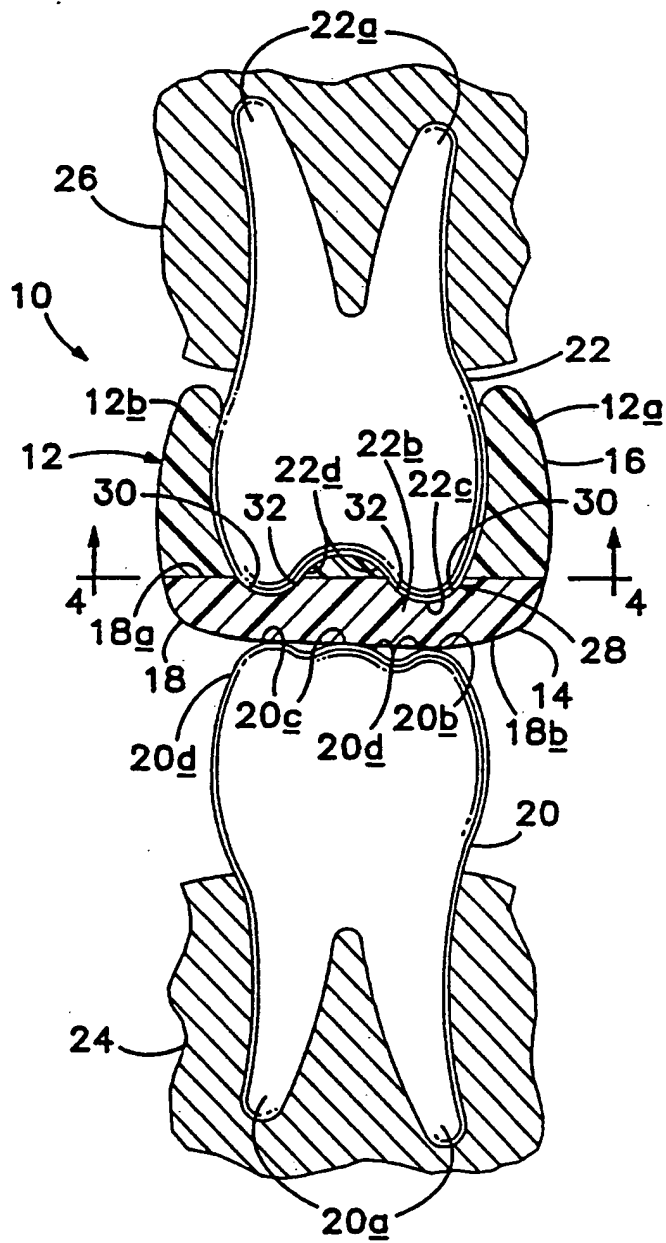


Fig. 3

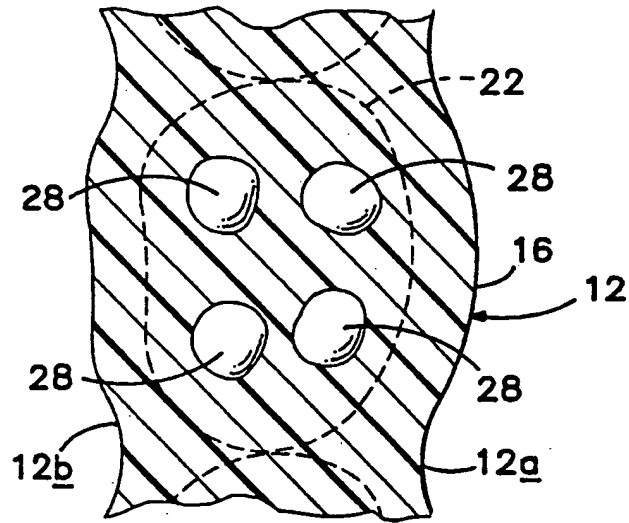


Fig. 4

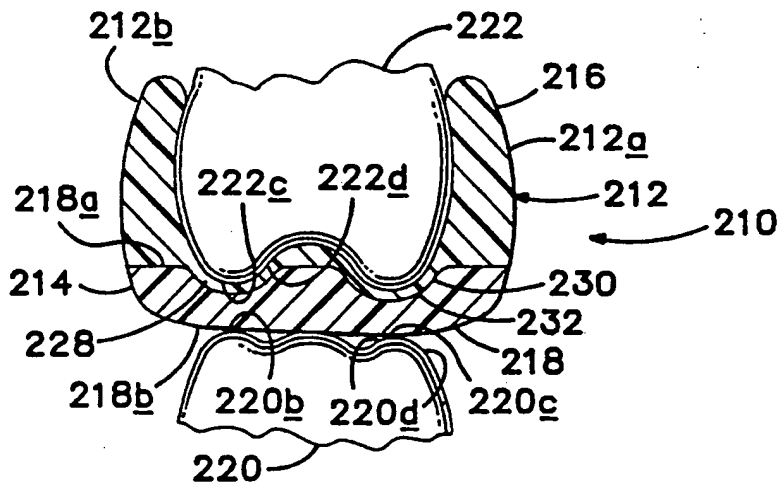


Fig. 5

SOFT RESILIENT INTEROCCLUSAL DENTAL APPLIANCE, METHOD OF FORMING SAME AND COMPOSITION FOR SAME

BACKGROUND AND SUMMARY OF THE INVENTION

The invention relates generally to dental appliances and synthetic compositions used to make them. More particularly, the invention concerns an improved interocclusal appliance which provides improved appliance retention and precise vertical and lateral positioning of the mandible, as well as a method of forming such appliance, and a curable composition for making dental appliances such as the invented appliance.

Interocclusal appliances, commonly referred to as splints, are well known, and are used to secure or hold in proper position (or desired range of positions) the mandible of a patient. Splints may be used for orthodontic treatment, as well as for orthopedic treatment of the bone, joints and supporting tissue associated with the mouth.

For example, splints are used to treat various conditions including temporomandibular joint (TMJ) dysfunction syndromes, myofascial pain dysfunction syndrome, and symptomatic or asymptomatic loss of tooth structure from subconscious parafunctional mandibular habits known as bruxism (grinding) or clenching. Splints are also used to reduce wear on teeth caused by metal or porcelain dental restorations during normal, functional or parafunctional mandibular movement. Splints may also be used as antisnoring devices to resolve snoring problems and obstructive sleep apnea (OSA).

Several unimaterial, conventional splints have been proposed but there are certain problems common to all of them. First, none of the so-called "soft" splints remain soft over time. Conventional splints harden over time due to their composition and/or due to leaching out of unreacted plasticizers present in them. Such hardening is a drawback because soft, resilient splints are preferred. Soft splints are preferred because they are more comfortable to wear than hard appliances, and because they provide improved retention of the splint held by the teeth.

A second drawback associated with such splints is that they are notoriously imprecise in terms of vertical and lateral positioning of the mandible under desired patient-bite conditions before they harden. Precise vertical and lateral positioning of the mandible is critical to proper orthodontic/orthopedic treatment. The section of conventional soft splints that is sandwiched by opposing sets of teeth is imprecise because it "gives" an irregular amount when the patient bites down under normal pressure, resulting in reduced TMJ stability in all dimensions.

Certain proposals have been made to make splints and other dental appliances out of two materials with differentiated hardnesses. Apparently, the idea is to use harder material in such appliances where harder material is needed and softer material where it is needed. For example, such proposals have been made in U.S. Pat. No. 4,448,735 to Huge, U.S. Pat. No. 3,404,056 to Baldwin, U.S. Pat. No. 2,934,823 to Preis and U.S. Pat. No. 2,789,351 to Gordon. However, none of the prior art proposals has been effective in overcoming the above-identified problems for splints.

Accordingly, it is a principal object of the present invention to provide an improved composition for a soft, persistently resilient, interocclusal dental appliance.

Another object is to provide such a composition that can be used for a dental appliance to impart in it the characteristic of being relatively soft and persistently resilient at mouth temperature for the working life of the appliance.

Yet another object is to provide an improved splint that adequately grasps the teeth of the user while also precisely retaining the mandible and/or TMJ in a desired position.

Another important object of the invention is to provide an improved splint that accommodates an immediate and accurate fit with the desired set of teeth jacketed by it and with the opposing set of teeth in contact with it.

Still another object is to provide an improved dental appliance that is comfortable to wear.

Yet another object is to provide a method of forming a plural-material interocclusal dental appliance from a unimaterial version of such appliance.

It is also an object of the invention to provide such an appliance that can be easily and cost-effectively manufactured.

In brief summary, one aspect of the invention includes a unitary plural-material, interocclusal dental appliance for use in connection with orthodontic/orthopedic treatment of the teeth and jaws of a patient's mouth. The appliance includes a first region made from a first material that provides a relatively hard, expanse with first and second surfaces, with the second surface being contactable by one such set of teeth. The second surface may be constructed with a substantially planar shape or with a shape that conforms generally to the cusps of such one set of teeth. A second region is joined to the first region, and is made from a second material that provides a relatively soft, persistently resilient enclosure for the other such set of teeth.

The second region includes plural zones, each of which is structured to allow an adjacent enclosed tooth to move toward the first surface of the first region, with such movement resulting in penetration of corresponding teeth into the relatively hard first material for a relatively precise distance. Such penetration defines lateral borders in the first material around such teeth so that the appliance accommodates relatively fixed lateral and vertical positioning of such enclosed teeth upon desired biting action by the patient.

Another aspect of the invention is a curable composition for making a soft, persistently resilient dental appliance. The composition includes a polymer component including butyl methacrylate polymer, and a monomer component including butyl methacrylate monomer. The soft, persistently resilient appliance formed from the composition of the present invention offers increased patient comfort and improved tooth retention.

Another aspect of the invention is a method of forming a unitary plural-material, interocclusal dental appliance for use in connection with orthodontic/orthopedic treatment of the teeth, jaws and mandible of a patient's mouth. The method is used in connection with conventional molding techniques usable to form a unimaterial interocclusal dental appliance in a corresponding cavity of a mold. The method of the invention includes the steps of (1) removing a first section of such conventionally formed unimaterial appliance to expose a surface of

a second section of it, (2) putting such unimaterial appliance back in the mold so that a void is formed, the void being defined by the removed first section, (3) filling the void with curable material that is different from the material used to form such unimaterial appliance, and (4) curing the newly formed appliance so that the two materials bond together along the surface of the second section, thus to form a unitary plural-material, interocclusal dental appliance with the first section made from material that is different from the second section.

These and other objects and advantages of the invention will be more clearly understood from a consideration of the accompanying drawings and the following description of the preferred embodiment.

BRIEF DESCRIPTION OF THE DRAWINGS

In the interest of clarity, it will be appreciated that the preferred embodiment of the invention is illustrated and described consistently, with respect to orientation, relative to its use in a patient's mouth. Thus, the orientation of the dental appliance illustrated in FIGS. 1 through 6 is described using anatomical terminology, as though the appliance were positioned in the mouth.

FIG. 1 is a top view of the preferred embodiment of the invention which is in place in the mouth of a patient, showing the upper teeth of the patient located in the appliance but blocking out all remaining portions of the mouth.

FIG. 2A is a right, buccal side view of the preferred embodiment of the invention shown in FIG. 1 with certain portions of the mouth shown.

FIG. 2B is a right, buccal side view similar to FIG. 2A only showing a second embodiment of the invention.

FIG. 3 is a fragmentary sectional view through line 3—3 of FIG. 1 which also shows portions of the gums and jaw of the mouth as well as a pair of opposing teeth.

FIG. 4 is a sectional view through lines 4—4 of FIG. 3.

FIG. 5 is like FIG. 3 only slightly more fragmentary and showing a third embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

FIGS. 1 and 2A depict top and side views of the invented unitary, plural-material interocclusal dental appliance, made in accordance with its preferred embodiment and indicated at 10. Preliminarily, it should be understood that appliance 10 may also be thought of as a TMJ dysfunction appliance. As will be understood, appliance 10 may be used by a patient for orthodontic/orthopedic treatment of the teeth, joints and bone associated with a patient's mouth.

Focusing first on FIG. 1, appliance 10 preferably has a generally U-shaped body 12. The inner U-shaped border 12a of body 12 corresponds to the tongue or lingual side of the appliance and the outer U-shaped border 12b corresponds to the cheek or buccal side of the appliance.

Referring to FIGS. 2-3, body 12 includes a first region 14, also referred to as an occlusal layer or a relatively hard occlusal layer, joined to a second region 16, also referred to as a jacketing section. Further discussion of techniques for forming body 12 will follow soon. As for joinder of the two regions, such joinder may be accomplished by any suitable method such as by bonding them together. First region 14 is formed from a first material and second region 16 is formed from a second

material, and both materials will be more particularly described below.

Referring to FIGS. 2A and 3, first region 14 takes the form of an expanse 18 with first and second surfaces 18a, 18b, respectively. Preferably, expanse 18 is constructed with a substantially planar second surface 18b but, as shown in FIG. 2B, a second embodiment of the invention is shown as an appliance 110 which includes expanse 118 being formed with a second surface 118b that conforms to the cusps of the lower teeth. The significance of constructing second surface 118b to conform with the cusps of the lower teeth will be described below.

Referring again to FIG. 3, second surface 18b is contactable by one set of teeth, such as the patient's lower teeth, one of which is shown at 20 in FIG. 3. Second region 16 takes the form of an enclosure (or jacketing section) for the patient's opposing set of teeth, such as the upper teeth, one of which is shown at 22. It should of course be understood that appliance 10 may be formed so that the jacketing section is usable on either the upper or lower set of teeth. Referring to teeth 20 and 22, each includes corresponding roots 20a, 22a which are shown positioned in lower and upper jaws 24, 26, respectively. Each tooth also includes corresponding cusps 20b, 22b. Each cusp may be thought of as having a top 20c, 22c and sides 20d, 22d, respectively.

Referring to FIGS. 3-4, one can see that second region 16 is formed with plural zones 28 which preferably take the form of openings that allow cusps 22b to contact first surface 18a of first region 18. Zones 28 may also be thought of as means for providing communication between selected ones of jacketed teeth (such as tooth 22 of FIG. 3) and first surface 18a of planar expanse 18. Referring for a moment to FIG. 5, a third embodiment of appliance is shown at 210 which includes plural zones 228 formed as relatively thin sections, i.e. with a thickness of about 0.5 mm-1.0 mm.

Referring to FIGS. 3 and 5 zones 28 and 228 each allow cusps 22b, 222b, to penetrate into first region 14, 214, respectively. Such penetration will be discussed further, but first it is important to understand certain details about the first and second material from which first and second regions 14, 16 (FIG. 3) are formed, respectively.

Referring again to FIGS. 1-3, first region 14 may be formed of any suitable relatively hard material that will allow teeth to penetrate into it only a relatively small, yet precise amount. Preferably, the first material is formed from known curable, acrylic-based polymer formulations that are commonly used in the field of orthodontics, such as polymethyl methacrylate (PMMA). PMMA, when cured, has a hardness that is greater than the to-be-described second material which is used to form second region 16.

Still referring to FIGS. 1-3, second region 16 is formed from a second material which forms another aspect of the present invention. This second material is characterized by a curable composition that is usable to make a soft, persistently resilient dental appliance. The composition includes a polymer component including butyl methacrylate polymer, and a monomer component including butyl methacrylate monomer. Preferably, the polymer component is about 20-80% by volume of the composition.

One example of a suitable composition for the second material is:

EXAMPLE 1

Butyl Methacrylate polymer (BMA-P)	10 g (9.35 ml)
Butyl Methacrylate monomer (BMA-M)	13.4 ml
Benzoyl Peroxide	0.2 g (0.15 ml)

The butyl methacrylate polymer (BMA-P) is available from E.I. Du Pont de Nemours & Co., Inc. and is marketed under the trademark ELVACITE 2044. The butyl methacrylate monomer (BMA-M) is available from Rohm and Haas Co. Benzoyl peroxide is available from Spectrum Chemical Mfg. Corp. of Gardena, Calif.

The above example composition may be mixed with suitable mixing means and, once mixed, is in a liquid state. A suitable mold may be formed using conventional processes such as those disclosed in U.S. Pat. No. 4,654,006 to Kusano et al., U.S. Pat. No. 4,080,412 to Colpitts et al. and U.S. Pat. No. 2,859,088 to Erdle et al., which patents are incorporated herein by reference. The liquid composition is injectable into the mold cavity by using a suitable syringe with suitable pressure, and then a curing operation is followed to form the desired appliance.

The newly formed appliance is persistently resilient based on in-mouth aging tests performed on appliances made from the above-described curable composition. Such tests gave the following results:

	Appliance A	Appliance B
Age	3 wks. old - unused	52 wks. old - used
Hardness*	68.8 (73° F.)	68.8 (73° F.)
(Shore D)	58.8 (99° F.)	59.2 (99° F.)

*Hardness readings for the above tests were averaged from seven readings taken at random locations.

Prior to forming the unitary, plural-material interocclusal appliance of the present invention, certain conventional steps are followed and then certain novel steps are also performed, the latter forming another aspect of the invention. The conventional steps involve the usual unimaterial dental-appliance-molding techniques disclosed in the above patents. These conventional techniques are also known as a "lost wax" method of forming a dental appliance.

Briefly, the techniques involve forming a suitable cavity in a mold (also called a flask) that corresponds to the shape of the desired splint. A wax pattern of the splint is formed and placed in a desired position on a stone impression of a desired set of the patient's teeth. Then, the impression and wax pattern are placed in a suitable mold with sprues, which is then filled with a suitable material, such as a hydrocolloid material. Thereafter, the mold is put in a heated water bath to boil out the wax pattern and also to solidify the hydrocolloid material. The resulting mold includes a cavity that defines the desired splint.

The novel steps of the invention include certain improved steps practiced in connection with the above conventional molding techniques. The above conventional techniques are usable to form a unimaterial interocclusal dental appliance in the corresponding cavity of the mold. The improved steps are practiced to form a unitary plural-material, interocclusal dental appliance from such unimaterial one.

From an overview, the method of the invention involves (1) removing a first section of the conventionally formed unimaterial interocclusal dental appliance to

expose a surface of a second section of it, (2) putting such unimaterial appliance back in the mold so that a void is defined by the removed first section, (3) filling the void with curable material that is different from the material used to form such unimaterial appliance, and (4) curing the newly formed appliance so that the two materials bond together along the surface of the second region, thus to form a unitary plural-material, interocclusal dental appliance with the first section made from material that is different from the second section.

Now focusing on further details of the method, after conventionally forming and curing the unimaterial appliance it is removed from the mold and cooled. Such appliance would have the appearance of appliance 10 of FIGS. 1, 2A and 3, only that it would be made solely of one material (such as the above-identified novel composition) instead of being made of two materials with corresponding regions like regions 14, 16. If the above-identified novel composition is used, it may be injected into the mold via the sprues and cured by placing the filled mold in a heated water bath (160° F.) for about two hours at 20 p.s.i.

It should be understood that appliance 10 in FIG. 3, which is a finished product, is now being used to further detail the steps used to practice the method of the invention. Generally, such steps involve forming a plural-material appliance (appliance 10) from a unimaterial appliance (undepicted). With reference to FIG. 3, imagine that it depicts a fragmentary section of stone teeth and gums, and a unimaterial appliance fitted on the upper stone teeth, all of which reside in a conventional mold (undepicted). Such unimaterial appliance would look like appliance 10 of FIG. 3 except that it would be unimaterial instead of having two regions 14, 16 made from different materials. Next, according to the method of the invention, the unimaterial appliance would be removed from the mold and a first section of it (corresponding to first region 14) would be removed with a suitable cutting device to expose a surface in a second section of it (corresponding to second region 16). Such exposed surface would correspond to the second-region side of the interface between first and second regions 14, 16 in FIG. 1. The result of such removal step would be to form zones in the unimaterial appliance like zones, or openings, 28 (FIGS. 3 and 4).

Then, the remainder of such unimaterial appliance is put back in the mold and a void is formed being defined by the just removed section of the appliance. For example, again referring to FIG. 3, the just cut unimaterial appliance would be put back in the mold in a position like that of appliance 10 with region 16 jacketing upper teeth such as tooth 22. However, the just cut unimaterial appliance would not have a section corresponding to region 14 because that would have been removed by the removing step. Next, suitable liquid PMMA is injected into the conventional mold (undepicted) via sprues to fill the void. Such liquid does not flow up through the openings in the surface of the second region because the stone teeth block such flow. To understand such relative positioning of the stone teeth and second section, FIG. 3 is again used to illustrate that the stone teeth would be positioned like upper tooth 22, which is seated in region 16 (corresponds to the second section of the unimaterial appliance). The cusps of tooth 22 block holes 28 by covering them.

Continuing with the description of the method of the invention, the conventional acrylic-based polymer in

the mold is cured and the product is demolded using conventional procedures. The product is characterized by having a first region made from the above-described, relatively hard first material (see region 14 of FIG. 3) joined, or bonded, to a second region made from the above-described soft, persistently resilient second material (see region 16 of FIG. 3).

To achieve an even greater bond between the two regions, a suitable bonding agent may be applied to the surface that was exposed by the removing step prior to placing the unimaterial appliance back in the mold for injection of the liquid PMMA.

Turning now to FIGS. 3-5, it will be appreciated that zones 28 (FIG. 3)/128 (FIG. 5) allow an adjacent enclosed tooth, such as tooth 22 (FIG. 3)/128 (FIG. 5), to move toward first surface 18a (FIG. 3)/118a (FIG. 5) of first region 14 (FIG. 3)/114 (FIG. 5). Such movement results in penetration of corresponding teeth such as tooth 22/122 into the relatively hard first material of first region 14/114 for a relatively precise distance. Such penetration defines lateral borders in the first material, such as those shown at 30, around such teeth. The result of both such types of tooth movement toward expanse 18 and such lateral-border formation is that appliance 10/110 accommodates relatively fixed vertical and lateral positioning of the mandible by enclosing teeth such as tooth 22/122.

Put another way, and referring to FIG. 3 only, zones 28 allow advancement of cusps 22b into first surface 18a, thereby to form a pocket 32 in the first surface whose shape conforms generally to the cusp and has dimensions spanning top 22c of the cusp and at least part way down sides 20d of the cusp. With such cusp advancement and pocket formation defining lateral borders 30 in the first material of first region 14 around such teeth, the appliance accommodates relatively fixed lateral and vertical positioning of such enclosed teeth upon desired biting action by the patient.

Referring back to FIG. 3, another advantage of appliance 10 of the present invention is shown by the fact that soft, persistently resilient region 16 provides for improved retention of jacketed teeth such as tooth 22 by extending apically to what are known as the undercuts of the tooth. Conventional hard splints cannot extend apically to the undercuts, and conventional "soft" splints are only able to extend to the undercuts before they eventually harden, at which point such extension is impossible.

Referring to FIGS. 3-4, it should also be understood that the exact number of zones 28 formed in a given area of region 16 may vary. To achieve the desired precise vertical and lateral positioning of the mandible described above, appliance 10 must be formed with at least three such zones, two being located substantially distally from the sagittal plane and one being located substantially mesially from the sagittal plane. For example, referring back to FIG. 1, such a requirement would necessitate forming two zones in region 16 adjacent teeth 34, 36 that are distal to the sagittal plane (represented by dashed line 38) and one zone adjacent tooth 40 that is mesial to the sagittal plane.

Referring to FIGS. 2A-2B, it should be apparent that the appliance of the present invention may be constructed with expanse 18 having substantially planar second surface 18b (FIG. 2A) or with expanse 118 having second surface 118b that conforms generally to the cusps of a desired set of teeth such as the lower teeth. The latter embodiment results in a splint that is usable as

a so-called anatomical splint, or repositioning splint, which is used to do what is known as "recapture the disk" associated with the TMJ. The former embodiment is for splints that are to be used as relaxation or stabilization splints.

Accordingly, while a preferred embodiment of the invention has been described herein, it is appreciated that modifications are possible that are within the scope of the invention.

It is claimed and desired to secure by letters patent:

1. A soft, persistently resilient interocclusal dental appliance, comprising:

a body made from an injectable, curable composition, with the composition including a polymer component consisting essentially of butyl methacrylate polymer, a monomer component consisting essentially of butyl methacrylate monomer and an effective amount of polymerizing agent.

2. The appliance of claim 1 wherein the polymer component is about 20-80% by volume of it.

3. The appliance of claim 2 being formed into a temporomandibular joint dysfunction appliance.

4. The appliance of claim 2 being formed into an anti-snoring device.

5. A soft, persistently resilient interocclusal dental appliance, comprising:

a body made from an injectable, curable composition, with the composition including a polymer component made substantially of butyl methacrylate polymer, a monomer component made substantially of butyl methacrylate monomer, and an effective amount of polymerizing agent.

6. The appliance of claim 5 wherein the polymer component is about 20-80% by volume of it.

7. The appliance of claim 6 being formed into a temporomandibular joint dysfunction appliance.

8. The appliance of claim 6 being formed into an anti-snoring device.

9. A soft, persistently resilient interocclusal dental appliance, comprising:

a body made from a curable composition, with the composition including a polymer component made substantially of butyl methacrylate polymer, a monomer component made substantially of butyl methacrylate monomer and an effective amount of polymerizing agent.

10. The appliance of claim 9 wherein the polymer component is about 20-80% by volume of it.

11. The appliance of claim 10 being formed into a temporomandibular joint dysfunction appliance.

12. The appliance of claim 10 being formed into an anti-snoring device.

13. A soft, persistently resilient, plural-material, interocclusal dental appliance, comprising:

a body including a hard region and a soft region, the soft region being made from a curable composition that includes a polymer component made substantially of butyl methacrylate polymer, a monomer component made substantially of butyl methacrylate monomer, an effective amount of polymerizing agent, and with the soft region formed from the composition being bondable to the hard region.

14. The appliance of claim 13 wherein the polymer component is about 20-80% by volume of it.

15. The appliance of claim 13 being formed into a temporomandibular joint dysfunction appliance.

16. The appliance of claim 13 being formed into an anti-snoring device.

17. An injectable, curable composition for making a soft, persistently resilient interocclusal dental appliance, comprising:

- a polymer component consisting essentially of butyl methacrylate polymer;
- a monomer component consisting essentially of butyl methacrylate monomer;
- an effective amount of polymerizing agent; and
- with the composition being sufficiently liquid to allow it to be injectable.

18. The composition of claim 17 wherein the polymer component is about 20-80% by volume of it.

19. An injectable, curable composition for making a soft, persistently resilient interocclusal dental appliance, comprising:

- a polymer component made substantially of butyl methacrylate polymer;
- a monomer component made substantially of butyl methacrylate monomer;

an effective amount of polymerizing agent; and with the composition being sufficiently liquid to allow it to be injectable.

20. The composition of claim 19 wherein the polymer component is about 20-80% by volume of it.

21. An injectable, curable composition for making a soft, persistently resilient region of a plural-material, interocclusal dental appliance, which appliance also includes a hard region, comprising:

- a polymer component made substantially of butyl methacrylate polymer;
- a monomer component made substantially of butyl methacrylate monomer;
- an effective amount of polymerizing agent; and
- with the composition being bondable to the hard region.

22. The composition of claim 21 wherein the polymer component is about 20-80% by volume of it.

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EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE